

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 2723  
OFFERED BY MR. COBURN, MR. SHADEGG, MR.  
GREENWOOD, MR. THOMAS, MRS. JOHNSON  
OF CONNECTICUT, MR. MCCRERY, MR. SALM-  
ON, MR. KOLBE, MR. PICKERING, AND MR.  
FLETCHER**

Strike all after the enacting clause and insert the  
following:

1     **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2           (a) SHORT TITLE.—This Act may be cited as the “Health Care Quality  
3     and Choice Act of 1999”.

4           (b) TABLE OF CONTENTS.—The table of contents of this Act is as fol-  
5     lows:

Sec. 1. Short title; table of contents.

TITLE I— AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

Sec. 101. Application to group health plans and group health insurance coverage.

Sec. 102. Application to individual health insurance coverage.

Sec. 103. Improving managed care.

“TITLE XXVIII—IMPROVING MANAGED CARE

“Subtitle A—Grievance and Appeals

“Sec. 2801. Utilization review activities.

“Sec. 2802. Internal appeals procedures.

“Sec. 2803. External appeals procedures.

“Sec. 2804. Establishment of a grievance process.

“Subtitle B—Access to Care

“Sec. 2811. Consumer choice option.

“Sec. 2812. Choice of health care professional.

“Sec. 2813. Access to emergency care.

“Sec. 2814. Access to specialty care.

“Sec. 2815. Access to obstetrical and gynecological care.

“Sec. 2816. Access to pediatric care.

“Sec. 2817. Continuity of care.

“Sec. 2818. Network adequacy.

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- “Sec. 2819. Access to experimental or investigational prescription drugs.
- “Sec. 2820. Coverage for individuals participating in approved cancer clinical trials.

## “Subtitle C—Access to Information

- “Sec. 2821. Patient access to information.

## “Subtitle D—Protecting the Doctor-Patient Relationship

- “Sec. 2831. Prohibition of interference with certain medical communications.
- “Sec. 2832. Prohibition of discrimination against providers based on licensure.
- “Sec. 2833. Prohibition against improper incentive arrangements.
- “Sec. 2834. Payment of clean claims.

## “Subtitle E—Definitions

- “Sec. 2841. Definitions.
- “Sec. 2842. Rule of construction.
- “Sec. 2843. Exclusions.
- “Sec. 2844. Coverage of limited scope plans.
- “Sec. 2845. Regulations.
- “Sec. 2846. Limitation on application of provisions relating to group health plans..

## TITLE II—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

- Sec. 201. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.
- Sec. 202. Improving managed care.

## “PART 8—IMPROVING MANAGED CARE

## “SUBPART A—GRIEVANCE AND APPEALS

- “Sec. 801. Utilization review activities.
- “Sec. 802. Internal appeals procedures.
- “Sec. 803. External appeals procedures.
- “Sec. 804. Establishment of a grievance process.

## “SUBPART B—ACCESS TO CARE

- “Sec. 812. Choice of health care professional.
- “Sec. 813. Access to emergency care.
- “Sec. 814. Access to specialty care.
- “Sec. 815. Access to obstetrical and gynecological care.
- “Sec. 816. Access to pediatric care.
- “Sec. 817. Continuity of care.
- “Sec. 818. Network adequacy.
- “Sec. 819. Access to experimental or investigational prescription drugs.
- “Sec. 820. Coverage for individuals participating in approved cancer clinical trials.

## “SUBPART C—ACCESS TO INFORMATION

- “Sec. 821. Patient access to information.

## “SUBPART D—PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

- “Sec. 831. Prohibition of interference with certain medical communications.
- “Sec. 832. Prohibition of discrimination against providers based on licensure.
- “Sec. 833. Prohibition against improper incentive arrangements.
- “Sec. 834. Payment of clean claims.

## “SUBPART E—DEFINITIONS

- “Sec. 841. Definitions.
- “Sec. 842. Rule of construction.
- “Sec. 843. Exclusions.
- “Sec. 844. Coverage of limited scope plans.
- “Sec. 845. Regulations.
- Sec. 203. Availability of court remedies.
- Sec. 204. Availability of binding arbitration.

## TITLE III— AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

- Sec. 301. Application to group health plans under the Internal Revenue Code of 1986.
- Sec. 302. Improving managed care.

## “CHAPTER 101—IMPROVING MANAGED CARE

## “SUBCHAPTER A—GRIEVANCE AND APPEALS.

- “Sec. 9901. Utilization review activities.
- “Sec. 9902. Internal appeals procedures.

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“Sec. 9903. External appeals procedures.

“Sec. 9904. Establishment of a grievance process.

“SUBCHAPTER B—ACCESS TO CARE

“Sec. 9912. Choice of health care professional.

“Sec. 9913. Access to emergency care.

“Sec. 9914. Access to specialty care.

“Sec. 9915. Access to obstetrical and gynecological care.

“Sec. 9916. Access to pediatric care.

“Sec. 9917. Continuity of care.

“Sec. 9918. Network adequacy.

“Sec. 9919. Access to experimental or investigational prescription drugs.

“Sec. 9920. Coverage for individuals participating in approved cancer clinical trials.

“SUBCHAPTER C—ACCESS TO INFORMATION

“Sec. 9921. Patient access to information.

“SUBCHAPTER D—PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

“Sec. 9931. Prohibition of interference with certain medical communications.

“Sec. 9932. Prohibition of discrimination against providers based on licensure.

“Sec. 9933. Prohibition against improper incentive arrangements.

“Sec. 9934. Payment of clean claims.

“SUBCHAPTER E—DEFINITIONS

“Sec. 9941. Definitions.

“Sec. 9942. Exclusions.

“Sec. 9943. Coverage of limited scope plans.

“Sec. 9944. Regulations.

TITLE IV—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

Sec. 401. Effective dates.

Sec. 402. Coordination in implementation.

TITLE V—OTHER PROVISIONS

Subtitle A—Protection of Information

Sec. 501. Protection for certain information.

Subtitle B—Other Matters

Sec. 511. Health care paperwork simplification.

**TITLE I— AMENDMENTS TO THE  
PUBLIC HEALTH SERVICE ACT**

**SEC. 101. APPLICATION TO GROUP HEALTH PLANS AND GROUP  
HEALTH INSURANCE COVERAGE.**

(a) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service Act is amended by adding at the end the following new section:

**“SEC. 2707. PATIENT PROTECTION STANDARDS.**

“(a) IN GENERAL.—Each group health plan shall comply with patient protection requirements under title XXVIII, and each health insurance issuer shall comply with patient protection requirements under such title with respect to group health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.

“(b) NOTICE.—A group health plan shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 (as in effect on the date of the enactment of the Health Care Quality and Choice Act of 1999) with respect to the requirements referred to in subsection (a) and a health insurance issuer shall comply with

1 such notice requirement as if such section applied to such issuer and such  
2 issuer were a group health plan.”.

3 (b) CONFORMING AMENDMENT.—Section 2721(b)(2)(A) of such Act  
4 (42 U.S.C. 300gg–21(b)(2)(A)) is amended by inserting “(other than sec-  
5 tion 2707)” after “requirements of such subparts”.

6 **SEC. 102. APPLICATION TO INDIVIDUAL HEALTH INSURANCE COV-**  
7 **ERAGE.**

8 Part B of title XXVII of the Public Health Service Act is amended by  
9 inserting after section 2752 the following new section:

10 **“SEC. 2753. PATIENT PROTECTION STANDARDS.**

11 “(a) IN GENERAL.—Each health insurance issuer shall comply with pa-  
12 tient protection requirements under title XXVIII with respect to individual  
13 health insurance coverage it offers, and such requirements shall be deemed  
14 to be incorporated into this subsection.

15 “(b) NOTICE.—A health insurance issuer under this part shall comply  
16 with the notice requirement under section 711(d) of the Employee Retirement  
17 Income Security Act of 1974 with respect to the requirements of such  
18 title as if such section applied to such issuer and such issuer were a group  
19 health plan.”.

20 **SEC. 103. IMPROVING MANAGED CARE.**

21 The Public Health Service Act is amended by adding at the end the  
22 following new title:

23 **“TITLE XXVIII—IMPROVING MANAGED**  
24 **CARE**

25 **“Subtitle A—Grievance and Appeals**

26 **“SEC. 2801. UTILIZATION REVIEW ACTIVITIES.**

27 “(a) COMPLIANCE WITH REQUIREMENTS.—

28 “(1) IN GENERAL.—A group health plan, and a health insurance  
29 issuer that provides health insurance coverage, shall conduct utilization  
30 review activities in connection with the provision of benefits under such  
31 plan or coverage only in accordance with a utilization review program  
32 that meets the requirements of this section.

33 “(2) USE OF OUTSIDE AGENTS.—Nothing in this section shall be  
34 construed as preventing a group health plan or health insurance issuer  
35 from arranging through a contract or otherwise for persons or entities  
36 to conduct utilization review activities on behalf of the plan or issuer,  
37 so long as such activities are conducted in accordance with a utilization  
38 review program that meets the requirements of this section.

39 “(3) UTILIZATION REVIEW DEFINED.—For purposes of this sec-  
40 tion, the terms ‘utilization review’ and ‘utilization review activities’  
41 mean procedures used to monitor or evaluate the use or coverage, clin-

1 ical necessity, appropriateness, efficacy, or efficiency of health care  
2 services, procedures or settings, and includes prospective review, con-  
3 current review, second opinions, case management, discharge planning,  
4 or retrospective review.

5 “(b) WRITTEN POLICIES AND CRITERIA.—

6 “(1) WRITTEN POLICIES.—A utilization review program shall be  
7 conducted consistent with written policies and procedures that govern  
8 all aspects of the program.

9 “(2) USE OF WRITTEN CRITERIA.—

10 “(A) IN GENERAL.—Such a program shall utilize written clin-  
11 ical review criteria developed with input from a range of appro-  
12 priate practicing physicians, as determined by the plan, pursuant  
13 to the program. Such criteria shall include written clinical review  
14 criteria that are based on valid clinical evidence where available  
15 and that are directed specifically at meeting the needs of at-risk  
16 populations and covered individuals with chronic conditions or se-  
17 vere illnesses, including gender-specific criteria and pediatric-spe-  
18 cific criteria where available and appropriate.

19 “(B) CONTINUING USE OF STANDARDS IN RETROSPECTIVE  
20 REVIEW.—If a health care service has been specifically pre-author-  
21 ized or approved for an enrollee under such a program, the pro-  
22 gram shall not, pursuant to retrospective review, revise or modify  
23 the specific standards, criteria, or procedures used for the utiliza-  
24 tion review for procedures, treatment, and services delivered to the  
25 enrollee during the same course of treatment.

26 “(C) REVIEW OF SAMPLE OF CLAIMS DENIALS.—Such a pro-  
27 gram shall provide for periodic evaluation at reasonable intervals  
28 of the clinical appropriateness of a sample of denials of claims for  
29 benefits.

30 “(c) CONDUCT OF PROGRAM ACTIVITIES.—

31 “(1) ADMINISTRATION BY HEALTH CARE PROFESSIONALS.—A uti-  
32 lization review program shall be administered by appropriate physician  
33 specialists who shall be selected by the plan or issuer and who shall  
34 oversee review decisions.

35 “(2) USE OF QUALIFIED, INDEPENDENT PERSONNEL.—

36 “(A) IN GENERAL.—A utilization review program shall pro-  
37 vide for the conduct of utilization review activities only through  
38 personnel who are qualified and have received appropriate training  
39 in the conduct of such activities under the program.

40 “(B) PROHIBITION OF CONTINGENT COMPENSATION AR-  
41 RANGEMENTS.—Such a program shall not, with respect to utiliza-

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tion review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that encourages denials of claims for benefits. This subparagraph shall not preclude any capitation arrangements between plans and providers.

“(C) PROHIBITION OF CONFLICTS.—Such a program shall not permit a health care professional who is providing health care services to an individual to perform utilization review activities in connection with the health care services being provided to the individual.

“(3) ACCESSIBILITY OF REVIEW.—Such a program shall provide that appropriate personnel performing utilization review activities under the program, including the utilization review administrator, are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.

“(4) LIMITS ON FREQUENCY.—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.

“(d) DEADLINE FOR DETERMINATIONS.—

“(1) PRIOR AUTHORIZATION SERVICES.—

“(A) IN GENERAL.—Except as provided in paragraph (2), in the case of a utilization review activity involving the prior authorization of health care items and services for an individual, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual’s designee and the individual’s health care provider by telephone and in printed or electronic form, no later than the deadline specified in subparagraph (B). The provider involved shall provide timely access to information relevant to the matter of the review decision.

“(B) DEADLINE.—

“(i) IN GENERAL.—Subject to clauses (ii) and (iii), the deadline specified in this subparagraph is 14 days after the earliest date as of which the request for prior authorization has been received and all necessary information has been provided.

1           “(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDI-  
2           TIONAL INFORMATION REQUIRED.—If a utilization review  
3           program—

4                 “(I) receives a request for a prior authorization,

5                 “(II) determines that additional information is nec-  
6                 essary to complete the review and make the determina-  
7                 tion on the request,

8                 “(III) notifies the requester, not later than 5 busi-  
9                 ness days after the date of receiving the request, of the  
10                need for such specified additional information, and

11               “(IV) requires the requester to submit specified in-  
12               formation not later than 2 business days after notifica-  
13               tion,

14           the deadline specified in this subparagraph is 14 days after  
15           the date the program receives the specified additional infor-  
16           mation, but in no case later than 28 days after the date of  
17           receipt of the request for the prior authorization. This clause  
18           shall not apply if the deadline is specified in clause (iii).

19               “(iii) EXPEDITED CASES.—In the case of a situation de-  
20               scribed in section 102(c)(1)(A), the deadline specified in this  
21               subparagraph is 48 hours after the time of the request for  
22               prior authorization.

23           “(2) ONGOING CARE.—

24               “(A) CONCURRENT REVIEW.—

25               “(i) IN GENERAL.—Subject to subparagraph (B), in the  
26               case of a concurrent review of ongoing care (including hos-  
27               pitalization), which results in a termination or reduction of  
28               such care, the plan must provide by telephone and in printed  
29               or electronic form notice of the concurrent review determina-  
30               tion to the individual or the individual’s designee and the in-  
31               dividual’s health care provider as soon as possible in accord-  
32               ance with the medical exigencies of the case, with sufficient  
33               time prior to the termination or reduction to allow for an ap-  
34               peal under section 102(c)(1)(A) to be completed before the  
35               termination or reduction takes effect.

36               “(ii) CONTENTS OF NOTICE.—Such notice shall include,  
37               with respect to ongoing health care items and services, the  
38               number of ongoing services approved, the new total of ap-  
39               proved services, the date of onset of services, and the next re-  
40               view date, if any, as well as a statement of the individual’s  
41               rights to further appeal.

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1 “(B) EXCEPTION.—Subparagraph (A) shall not be inter-  
2 preted as requiring plans or issuers to provide coverage of care  
3 that would exceed the coverage limitations for such care.

4 “(3) PREVIOUSLY PROVIDED SERVICES.—In the case of a utiliza-  
5 tion review activity involving retrospective review of health care services  
6 previously provided for an individual, the utilization review program  
7 shall make a determination concerning such services, and provide notice  
8 of the determination to the individual or the individual’s designee and  
9 the individual’s health care provider by telephone and in printed or  
10 electronic form, within 30 days of the date of receipt of information  
11 that is reasonably necessary to make such determination, but in no  
12 case later than 60 days after the date of receipt of the claim for bene-  
13 fits.

14 “(4) FAILURE TO MEET DEADLINE.—In a case in which a group  
15 health plan or health insurance issuer fails to make a determination  
16 on a claim for benefit under paragraph (1), (2)(A), or (3) by the appli-  
17 cable deadline established under the respective paragraph, the failure  
18 shall be treated under this subtitle as a denial of the claim as of the  
19 date of the deadline.

20 “(5) REFERENCE TO SPECIAL RULES FOR EMERGENCY SERVICES,  
21 MAINTENANCE CARE, POST-STABILIZATION CARE, AND EMERGENCY AM-  
22 BULANCE SERVICES.—For waiver of prior authorization requirements  
23 in certain cases involving emergency services, maintenance care and  
24 post-stabilization care, and emergency ambulance services, see sub-  
25 sections (a)(1), (b), and (c)(1) of section 113, respectively.

26 “(e) NOTICE OF DENIALS OF CLAIMS FOR BENEFITS.—

27 “(1) IN GENERAL.—Notice of a denial of claims for benefits under  
28 a utilization review program shall be provided in printed or electronic  
29 form and written in a manner calculated to be understood by the par-  
30 ticipant, beneficiary, or enrollee and shall include—

31 “(A) the reasons for the denial (including the clinical ration-  
32 ale);

33 “(B) instructions on how to initiate an appeal under section  
34 102; and

35 “(C) notice of the availability, upon request of the individual  
36 (or the individual’s designee) of the clinical review criteria relied  
37 upon to make such denial.

38 “(2) SPECIFICATION OF ANY ADDITIONAL INFORMATION.—Such a  
39 notice shall also specify what (if any) additional necessary information  
40 must be provided to, or obtained by, the person making the denial in  
41 order to make a decision on such an appeal.



1 “(f) CLAIM FOR BENEFITS AND DENIAL OF CLAIM FOR BENEFITS DE-  
2 FINED.—For purposes of this subtitle:

3 “(1) CLAIM FOR BENEFITS.—The term ‘claim for benefits’ means  
4 any request for coverage (including authorization of coverage), or for  
5 payment in whole or in part, for an item or service under a group  
6 health plan or health insurance coverage.

7 “(2) DENIAL OF CLAIM FOR BENEFITS.—The term ‘denial’ means,  
8 with respect to a claim for benefits, a denial, or a failure to act on  
9 a timely basis upon, in whole or in part, the claim for benefits and in-  
10 cludes a failure to provide or pay for benefits (including items and serv-  
11 ices) required to be provided or paid for under this title.

12 **“SEC. 2802. INTERNAL APPEALS PROCEDURES.**

13 “(a) RIGHT OF REVIEW.—

14 “(1) IN GENERAL.—Each group health plan, and each health in-  
15 surance issuer offering health insurance coverage—

16 “(A) shall provide adequate notice in written or electronic  
17 form to any participant or beneficiary under such plan, or enrollee  
18 under such coverage, whose claim for benefits under the plan or  
19 coverage has been denied “(within the meaning of section  
20 2801(f)(2)), setting forth the specific reasons for such denial of  
21 claim for benefits and rights to any further review or appeal, writ-  
22 ten in layman’s terms to be understood by the participant, bene-  
23 ficiary, or enrollee; and

24 “(B) shall afford such a participant, beneficiary, or enrollee  
25 (and any provider or other person acting on behalf of such an indi-  
26 vidual with the individual’s consent or without such consent if the  
27 individual is medically unable to provide such consent) who is dis-  
28 satisfied with such a denial of claim for benefits a reasonable op-  
29 portunity of not less than 180 days to request and obtain a full  
30 and fair review by a named fiduciary (with respect to such plan)  
31 or named appropriate individual (with respect to such coverage) of  
32 the decision denying the claim.

33 “(2) TREATMENT OF ORAL REQUESTS.—The request for review  
34 under paragraph (1)(B) may be made orally, but, in the case of an oral  
35 request, shall be followed by a request in written or electronic form.

36 “(b) INTERNAL REVIEW PROCESS.—

37 “(1) CONDUCT OF REVIEW.—

38 “(A) IN GENERAL.—A review of a denial of claim under this  
39 section shall be made by an individual (who shall be a physician  
40 in a case involving medical judgment) who has been selected by  
41 the plan or issuer and who did not make the initial denial in the

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1 internally appealable decision, except that in the case of limited  
2 scope coverage (as defined in subparagraph (B)) an appropriate  
3 specialist shall review the decision.

4 “(B) LIMITED SCOPE COVERAGE DEFINED.—For purposes of  
5 subparagraph (A), the term ‘limited scope coverage’ means a  
6 group health plan or health insurance coverage the only benefits  
7 under which are for benefits described in section 2791(c)(2)(A) of  
8 the Public Health Service Act (42 U.S.C. 300gg–91(c)(2)).

9 “(2) TIME LIMITS FOR INTERNAL REVIEWS.—

10 “(A) IN GENERAL.—Having received such a request for re-  
11 view of a denial of claim, the plan or issuer shall, in accordance  
12 with the medical exigencies of the case but not later than the  
13 deadline specified in subparagraph (B), complete the review on the  
14 denial and transmit to the participant, beneficiary, enrollee, or  
15 other person involved a decision that affirms, reverses, or modifies  
16 the denial. If the decision does not reverse the denial, the plan or  
17 issuer shall transmit, in printed or electronic form, a notice that  
18 sets forth the grounds for such decision and that includes a de-  
19 scription of rights to any further appeal. Such decision shall be  
20 treated as the final decision of the plan. Failure to issue such a  
21 decision by such deadline shall be treated as a final decision af-  
22 firming the denial of claim.

23 “(B) DEADLINE.—

24 “(i) IN GENERAL.—Subject to clauses (ii) and (iii), the  
25 deadline specified in this subparagraph is 14 days after the  
26 earliest date as of which the request for prior authorization  
27 has been received and all necessary information has been pro-  
28 vided. The provider involved shall provide timely access to in-  
29 formation relevant to the matter of the review decision.

30 “(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDI-  
31 TIONAL INFORMATION REQUIRED.—If a group health plan or  
32 health insurance issuer—

33 “(I) receives a request for internal review,

34 “(II) determines that additional information is nec-  
35 essary to complete the review and make the determina-  
36 tion on the request,

37 “(III) notifies the requester, not later than 5 busi-  
38 ness days after the date of receiving the request, of the  
39 need for such specified additional information, and

40 “(IV) requires the requester to submit specified in-  
41 formation not later than 48 hours after notification,

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1 the deadline specified in this subparagraph is 14 days after  
2 the date the plan or issuer receives the specified additional in-  
3 formation, but in no case later than 28 days after the date  
4 of receipt of the request for the internal review. This clause  
5 shall not apply if the deadline is specified in clause (iii).

6 “(iii) EXPEDITED CASES.—In the case of a situation de-  
7 scribed in subsection (c)(1)(A), the deadline specified in this  
8 subparagraph is 48 hours after the time of request for review

9 “(c) EXPEDITED REVIEW PROCESS.—

10 “(1) IN GENERAL.—A group health plan, and a health insurance  
11 issuer, shall establish procedures in writing for the expedited consid-  
12 eration of requests for review under subsection (b) in situations—

13 “(A) in which, as determined by the plan or issuer or as cer-  
14 tified in writing by a treating physician, the application of the nor-  
15 mal timeframe for making the determination could seriously jeop-  
16 ardize the life or health of the participant, beneficiary, or enrollee  
17 or such individual’s ability to regain maximum function; or

18 “(B) described in section 2801(d)(2) (relating to requests for  
19 continuation of ongoing care which would otherwise be reduced or  
20 terminated).

21 “(2) PROCESS.—Under such procedures—

22 “(A) the request for expedited review may be submitted orally  
23 or in writing by an individual or provider who is otherwise entitled  
24 to request the review;

25 “(B) all necessary information, including the plan’s or  
26 issuer’s decision, shall be transmitted between the plan or issuer  
27 and the requester by telephone, facsimile, or other similarly expe-  
28 ditious available method; and

29 “(C) the plan or issuer shall expedite the review in the case  
30 of any of the situations described in subparagraph (A) or (B) of  
31 paragraph (1).

32 “(3) DEADLINE FOR DECISION.—The decision on the expedited re-  
33 view must be made and communicated to the parties as soon as pos-  
34 sible in accordance with the medical exigencies of the case, and in no  
35 event later than 48 hours after the time of receipt of the request for  
36 expedited review, except that in a case described in paragraph (1)(B),  
37 the decision must be made before the end of the approved period of  
38 care.

39 “(d) WAIVER OF PROCESS.—A plan or issuer may waive its rights for  
40 an internal review under subsection (b). In such case the participant, bene-  
41 ficiary, or enrollee involved (and any designee or provider involved) shall be

1 relieved of any obligation to complete the review involved and may, at the  
2 option of such participant, beneficiary, enrollee, designee, or provider, pro-  
3 ceed directly to seek further appeal through any applicable external appeals  
4 process.

5 **“SEC. 2803. EXTERNAL APPEALS PROCEDURES.**

6 “(a) RIGHT TO EXTERNAL APPEAL.—

7 “(1) IN GENERAL.—A group health plan, and a health insurance  
8 issuer offering health insurance coverage, shall provide for an external  
9 appeals process that meets the requirements of this section in the case  
10 of an externally appealable decision described in paragraph (2), for  
11 which a timely appeal is made (within a reasonable period not to exceed  
12 365 days) either by the plan or issuer or by the participant, bene-  
13 ficiary, or enrollee (and any provider or other person acting on behalf  
14 of such an individual with the individual’s consent or without such con-  
15 sent if such an individual is medically unable to provide such consent).

16 “(2) EXTERNALLY APPEALABLE DECISION DEFINED.—

17 “(A) IN GENERAL.—For purposes of this section, the term  
18 ‘externally appealable decision’ means a denial of claim for bene-  
19 fits (as defined in section 2801(f)(2)), if—

20 “(i) the item or service involved is covered under the  
21 plan or coverage,

22 “(ii) the amount involved exceeds \$100, increased or de-  
23 creased, for each calendar year that ends after December 31,  
24 2001, by the same percentage as the percentage by which the  
25 medical care expenditure category of the Consumer Price  
26 Index for All Urban Consumers (United States city average),  
27 published by the Bureau of Labor Statistics, for September  
28 of the preceding calendar year has increased or decreased  
29 from such index for September 2000, and

30 “(iii) the requirements of subparagraph (B) are met with  
31 respect to such denial.

32 Such term also includes a failure to meet an applicable deadline  
33 for internal review under section 2802 or such standards as are  
34 established pursuant to section 2818.

35 “(B) REQUIREMENTS.—For purposes of subparagraph  
36 (A)(iii), the requirements of this subparagraph are met with re-  
37 spect to a denial of a claim for benefits if—

38 “(i) the denial is based in whole or in part on a decision  
39 that the item or service is not medically necessary or appro-  
40 priate or is investigational or experimental, or

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1 “(ii) in such denial, the decision as to whether an item  
2 or service is covered involves a medical judgment.

3 “(C) EXCLUSIONS.—The term ‘externally appealable decision’  
4 does not include—

5 “(i) specific exclusions or express limitations on the  
6 amount, duration, or scope of coverage; or

7 “(ii) a decision regarding eligibility for any benefits.

8 “(3) EXHAUSTION OF INTERNAL REVIEW PROCESS.—Except as  
9 provided under section 2802(d), a plan or issuer may condition the use  
10 of an external appeal process in the case of an externally appealable  
11 decision upon a final decision in an internal review under section 2802,  
12 but only if the decision is made in a timely basis consistent with the  
13 deadlines provided under this subtitle.

14 “(4) FILING FEE REQUIREMENT.—

15 “(A) IN GENERAL.—A plan or issuer may condition the use  
16 of an external appeal process upon payment in advance to the plan  
17 or issuer of a \$25 filing fee.

18 “(B) REFUNDING FEE IN CASE OF SUCCESSFUL APPEALS.—  
19 The plan or issuer shall refund payment of the filing fee under  
20 this paragraph if the recommendation of the external appeal entity  
21 is to reverse the denial of a claim for benefits which is the subject  
22 of the appeal.

23 “(b) GENERAL ELEMENTS OF EXTERNAL APPEALS PROCESS.—

24 “(1) USE OF QUALIFIED EXTERNAL APPEAL ENTITY.—

25 “(A) IN GENERAL.—The external appeal process under this  
26 section of a plan or issuer shall be conducted between the plan or  
27 issuer and one or more qualified external appeal entities (as de-  
28 fined in subsection (c)). Nothing in this subsection shall be con-  
29 strued as requiring that such procedures provide for the selection  
30 for any plan of more than one such entity.

31 “(B) LIMITATION ON PLAN OR ISSUER SELECTION.—The Sec-  
32 retary shall implement procedures to assure that the selection  
33 process among qualified external appeal entities will not create any  
34 incentives for external appeal entities to make a decision in a bi-  
35 ased manner.

36 “(C) OTHER TERMS AND CONDITIONS.—The terms and con-  
37 ditions of this paragraph shall be consistent with the standards  
38 the Secretary shall establish to assure there is no real or apparent  
39 conflict of interest in the conduct of external appeal activities. All  
40 costs of the process (except those incurred by the participant, ben-  
41 eficiary, enrollee, or treating professional in support of the appeal)

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1 shall be paid by the plan or issuer, and not by the participant,  
2 beneficiary, or enrollee. The previous sentence shall not be con-  
3 strued as applying to the imposition of a filing fee under sub-  
4 section (a)(4).

5 “(2) ELEMENTS OF PROCESS.—An external appeal process shall  
6 be conducted consistent with standards established by the Secretary  
7 that include at least the following:

8 “(A) FAIR AND DE NOVO DETERMINATION.—The process  
9 shall provide for a fair, de novo determination described in sub-  
10 paragraph (B) based on evidence described in subparagraphs (C)  
11 and (D).

12 “(B) STANDARD OF REVIEW.—An external appeal entity shall  
13 determine whether the plan’s or issuer’s decision is appropriate for  
14 the medical condition of the patient involved (as determined by the  
15 entity) taking into account as of the time of the entity’s deter-  
16 mination the patient’s medical condition and any relevant and reli-  
17 able evidence the entity obtains under subparagraphs (C) and (D).  
18 If the entity determines the decision is appropriate for such condi-  
19 tion, the entity shall affirm the decision and to the extent that the  
20 entity determines the decision is not appropriate for such condi-  
21 tion, the entity shall reverse the decision. Nothing in this subpara-  
22 graph shall be construed as providing for coverage of items or  
23 services not provided or covered by the plan or issuer.

24 “(C) REQUIRED CONSIDERATION OF CERTAIN MATTERS.—In  
25 making such determination, the external appeal entity shall con-  
26 sider, but not be bound by—

27 “(i) any language in the plan or coverage document re-  
28 lating to the definitions of the terms medical necessity, medi-  
29 cally necessary or appropriate, or experimental, investiga-  
30 tional, or related terms;

31 “(ii) the decision made by the plan or issuer upon inter-  
32 nal review under section 2802 and any guidelines or stand-  
33 ards used by the plan or issuer in reaching such decision; and

34 “(iii) the opinion of the individual’s treating physician or  
35 health care professional.

36 The entity also shall consider any personal health and medical in-  
37 formation supplied with respect to the individual whose denial of  
38 claim for benefits has been appealed. The entity also shall consider  
39 the results of studies that meet professionally recognized stand-  
40 ards of validity and replicability or that have been published in  
41 peer-reviewed journals.

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1 “(D) ADDITIONAL EVIDENCE.—Such entity may also take  
2 into consideration but not be limited to the following evidence (to  
3 the extent available):

4 “(i) The results of professional consensus conferences.

5 “(ii) Practice and treatment policies.

6 “(iii) Community standard of care.

7 “(iv) Generally accepted principles of professional med-  
8 ical practice consistent with the best practice of medicine.

9 “(v) To the extent that the entity determines it to be  
10 free of any conflict of interest, the opinions of individuals who  
11 are qualified as experts in one or more fields of health care  
12 which are directly related to the matters under appeal.

13 “(vi) To the extent that the entity determines it to be  
14 free of any conflict of interest, the results of peer reviews con-  
15 ducted by the plan or issuer involved.

16 “(E) DETERMINATION CONCERNING EXTERNALLY APPEAL-  
17 ABLE DECISIONS.—

18 “(i) IN GENERAL.—A qualified external appeal entity  
19 shall determine—

20 “(I) whether a denial of claim for benefits is an ex-  
21 ternally appealable decision (within the meaning of sub-  
22 section (a)(2));

23 “(II) whether an externally appealable decision in-  
24 volves an expedited appeal;

25 “(III) for purposes of initiating an external review,  
26 whether the internal review process has been completed;  
27 and

28 “(IV) whether the item or services is covered under  
29 the plan or coverage.

30 “(ii) CONSTRUCTION.—Nothing in a determination by a  
31 qualified external appeal entity under this section shall be  
32 construed as authorizing, or providing for, coverage of items  
33 and services for which benefits are not provided under the  
34 plan or coverage.

35 “(F) OPPORTUNITY TO SUBMIT EVIDENCE.—Each party to  
36 an externally appealable decision may submit evidence related to  
37 the issues in dispute.

38 “(G) PROVISION OF INFORMATION.—The plan or issuer in-  
39 volved shall provide to the external appeal entity timely access to  
40 information and to provisions of the plan or health insurance cov-  
41 erage relating to the matter of the externally appealable decision,

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1 as determined by the entity. The provider involved shall provide  
2 to the external appeal entity timely access to information relevant  
3 to the matter of the externally appealable decision, as determined  
4 by the entity.

5 “(H) TIMELY DECISIONS.—A determination by the external  
6 appeal entity on the decision shall—

7 “(i) be made orally or in written or electronic form and,  
8 if it is made orally, shall be supplied to the parties in written  
9 or electronic form as soon as possible;

10 “(ii) be made in accordance with the medical exigencies  
11 of the case involved, but in no event later than 21 days after  
12 the date (or, in the case of an expedited appeal, 48 hours  
13 after the time) of requesting an external appeal of the deci-  
14 sion;

15 “(iii) state, in layperson’s language, the scientific ration-  
16 ale for such determination as well as the basis for such deter-  
17 mination, including, if relevant, any basis in the terms or con-  
18 ditions of the plan or coverage; and

19 “(iv) inform the participant, beneficiary, or enrollee of  
20 the individual’s rights (including any limitation on such  
21 rights) to seek binding arbitration or further review by the  
22 courts (or other process) of the external appeal determination.

23 “(I) COMPLIANCE WITH DETERMINATION.—If the external  
24 appeal entity determines that a denial of a claim for benefits was  
25 not reasonable and reverses the denial, the plan or issuer—

26 “(i) shall (upon the receipt of the determination) author-  
27 ize the provision or payment for benefits in accordance with  
28 such determination;

29 “(ii) shall take such actions as may be necessary to pro-  
30 vide or pay for benefits (including items or services) in a  
31 timely manner consistent with such determination; and

32 “(iii) shall submit information to the entity documenting  
33 compliance with the entity’s determination and this subpara-  
34 graph.

35 “(J) CONSTRUCTION.—Nothing in this paragraph shall be  
36 construed as providing for coverage of items and services for which  
37 benefits are not provided under the plan or coverage.

38 “(c) QUALIFICATIONS OF EXTERNAL APPEAL ENTITIES.—

39 “(1) IN GENERAL.—For purposes of this section, the term ‘quali-  
40 fied external appeal entity’ means, in relation to a plan or issuer, an



entity that is certified under paragraph (2) as meeting the following requirements:

“(A) The entity meets the independence requirements of paragraph (3).

“(B) The entity conducts external appeal activities through at least three clinical peers who are practicing physicians.

“(C) The entity has sufficient medical, legal, and other expertise and sufficient staffing to conduct external appeal activities for the plan or issuer on a timely basis consistent with subsection (b)(2)(G).

“(2) INITIAL CERTIFICATION OF EXTERNAL APPEAL ENTITIES.—

“(A) IN GENERAL.—In order to be treated as a qualified external appeal entity with respect to a group health plan or health insurance issuer operating in a State, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting such requirements—

“(i) by the applicable State authority (or under a process recognized or approved by such authority); or

“(ii) if the State has not established a certification and recertification process for such entities, by the Secretary, under a process recognized or approved by the Secretary, or to the extent provided in subparagraph (C)(ii), by a qualified private standard-setting organization (certified under such subparagraph), if elected by the entity.

“(B) RECERTIFICATION PROCESS.—The Secretary shall develop standards for the recertification of external appeal entities. Such standards shall include a review of—

“(i) the number of cases reviewed;

“(ii) a summary of the disposition of those cases;

“(iii) the length of time in making determinations on those cases;

“(iv) updated information of what was required to be submitted as a condition of certification for the entity’s performance of external appeal activities; and

“(v) information necessary to assure that the entity meets the independence requirements (described in paragraph (3)) with respect to plans and issuers for which it conducts external review activities.

“(C) CERTIFICATION OF QUALIFIED PRIVATE STANDARD-SETTING ORGANIZATIONS.—For purposes of subparagraph (A)(ii), the Secretary may provide for a process for certification (and periodic

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1 recertification) of qualified private standard-setting organizations  
2 which provide for certification of external appeal entities. Such an  
3 organization shall only be certified if the organization does not  
4 certify an external appeal entity unless it meets standards as least  
5 as stringent as the standards required for certification of such an  
6 entity by the Secretary under subparagraph (A)(ii).

7 “(3) INDEPENDENCE REQUIREMENTS.—

8 “(A) IN GENERAL.—A clinical peer or other entity meets the  
9 independence requirements of this paragraph if—

10 “(i) the peer or entity is not affiliated with any related  
11 party;

12 “(ii) any compensation received by such peer or entity in  
13 connection with the external review is reasonable and not con-  
14 tingent on any decision rendered by the peer or entity;

15 “(iii) the plan and the issuer (if any) have no recourse  
16 against the peer or entity in connection with the external re-  
17 view; and

18 “(iv) the peer or entity does not otherwise have a conflict  
19 of interest with a related party.

20 “(B) RELATED PARTY.—For purposes of this paragraph, the  
21 term ‘related party’ means—

22 “(i) with respect to—

23 “(I) a group health plan or health insurance cov-  
24 erage offered in connection with such a plan, the plan or  
25 the health insurance issuer offering such coverage, or

26 “(II) individual health insurance coverage, the  
27 health insurance issuer offering such coverage,  
28 or any plan sponsor, fiduciary, officer, director, or manage-  
29 ment employee of such plan or issuer;

30 “(ii) the health care professional that provided the health  
31 care involved in the coverage decision;

32 “(iii) the institution at which the health care involved in  
33 the coverage decision is provided; or

34 “(iv) the manufacturer of any drug or other item that  
35 was included in the health care involved in the coverage deci-  
36 sion.

37 “(C) AFFILIATED.—For purposes of this paragraph, the term  
38 ‘affiliated’ means, in connection with any peer or entity, having a  
39 familial, financial, or fiduciary relationship with such peer or enti-  
40 ty.

## 19

1           “(4) LIMITATION ON LIABILITY OF REVIEWERS.—No qualified ex-  
2       ternal appeal entity having a contract with a plan or issuer under this  
3       part and no person who is employed by any such entity or who fur-  
4       nishes professional services to such entity, shall be held by reason of  
5       the performance of any duty, function, or activity required or author-  
6       ized pursuant to this section, to have violated any criminal law, or to  
7       be civilly liable under any law of the United States or of any State (or  
8       political subdivision thereof) if due care was exercised in the perform-  
9       ance of such duty, function, or activity and there was no actual malice  
10      or gross misconduct in the performance of such duty, function, or ac-  
11      tivity.

12      “(d) EXTERNAL APPEAL DETERMINATION BINDING ON PLAN.—

13           “(1) IN GENERAL.—The determination by an external appeal enti-  
14      ty shall be binding on the plan (and issuer, if any) involved in the de-  
15      termination.

16           “(2) PROTECTION OF LEGAL RIGHTS.—Nothing in this subtitle  
17      shall be construed as removing any legal rights of participants, bene-  
18      ficiaries, enrollees, and others under State or Federal law, including the  
19      right to file judicial actions to enforce rights.

20      “(e) PENALTIES AGAINST AUTHORIZED OFFICIALS FOR REFUSING TO  
21      AUTHORIZE THE DETERMINATION OF AN EXTERNAL APPEAL ENTITY.—

22           “(1) MONETARY PENALTIES.—In any case in which the deter-  
23      mination of an external appeal entity is not followed in a timely fashion  
24      by a group health plan, or by a health insurance issuer offering health  
25      insurance coverage, any named fiduciary who, acting in the capacity of  
26      authorizing the benefit, causes such refusal may, in the discretion in  
27      a court of competent jurisdiction, be liable to an aggrieved participant,  
28      beneficiary, or enrollee for a civil penalty in an amount of up to \$1,000  
29      a day from the date on which the determination was transmitted to the  
30      plan or issuer by the external appeal entity until the date the refusal  
31      to provide the benefit is corrected.

32           “(2) CEASE AND DESIST ORDER AND ORDER OF ATTORNEY’S  
33      FEES.—In any action described in paragraph (1) brought by a partici-  
34      pant, beneficiary, or enrollee with respect to a group health plan, or  
35      a health insurance issuer offering health insurance coverage, in which  
36      a plaintiff alleges that a person referred to in such paragraph has  
37      taken an action resulting in a refusal of a benefit determined by an  
38      external appeal entity in violation of such terms of the plan, coverage,  
39      or this subtitle, or has failed to take an action for which such person  
40      is responsible under the plan, coverage, or this title and which is nec-  
41      essary under the plan or coverage for authorizing a benefit, the court

1 shall cause to be served on the defendant an order requiring the  
2 defendant—

3 “(A) to cease and desist from the alleged action or failure to  
4 act; and

5 “(B) to pay to the plaintiff a reasonable attorney’s fee and  
6 other reasonable costs relating to the prosecution of the action on  
7 the charges on which the plaintiff prevails.

8 “(f) PROTECTION OF LEGAL RIGHTS.—Nothing in this subtitle shall be  
9 construed as removing or limiting any legal rights of participants, bene-  
10 ficiaries, enrollees, and others under State or Federal law (including section  
11 502 of the Employee Retirement Income Security Act of 1974), including  
12 the right to file judicial actions to enforce rights.

13 **“SEC. 2804. ESTABLISHMENT OF A GRIEVANCE PROCESS.**

14 “(a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

15 “(1) IN GENERAL.—A group health plan, and a health insurance  
16 issuer in connection with the provision of health insurance coverage,  
17 shall establish and maintain a system to provide for the presentation  
18 and resolution of oral and written grievances brought by individuals  
19 who are participants, beneficiaries, or enrollees, or health care pro-  
20 viders or other individuals acting on behalf of an individual and with  
21 the individual’s consent or without such consent if the individual is  
22 medically unable to provide such consent, regarding any aspect of the  
23 plan’s or issuer’s services.

24 “(2) GRIEVANCE DEFINED.—In this section, the term ‘grievance’  
25 means any question, complaint, or concern brought by a participant,  
26 beneficiary, or enrollee that is not a claim for benefits.

27 “(b) GRIEVANCE SYSTEM.—Such system shall include the following  
28 components with respect to individuals who are participants, beneficiaries,  
29 or enrollees:

30 “(1) Written notification to all such individuals and providers of  
31 the telephone numbers and business addresses of the plan or issuer  
32 personnel responsible for resolution of grievances and appeals.

33 “(2) A system to record and document, over a period of at least  
34 3 previous years beginning two months after the date of the enactment  
35 of this Act, all grievances and appeals made and their status.

36 “(3) A process providing processing and resolution of grievances  
37 within 60 days.

38 “(4) Procedures for follow-up action, including the methods to in-  
39 form the person making the grievance of the resolution of the griev-  
40 ance.

1 Grievances are not subject to appeal under the previous provisions of this  
2 subtitle.

### 3 **“Subtitle B—Access to Care**

#### 4 **“SEC. 2811. CONSUMER CHOICE OPTION.**

5 “(a) IN GENERAL.—If a health insurance issuer offers to enrollees  
6 health insurance coverage in connection with a group health plan which pro-  
7 vides for coverage of services only if such services are furnished through  
8 health care professionals and providers who are members of a network of  
9 health care professionals and providers who have entered into a contract  
10 with the issuer to provide such services, the issuer shall also offer to such  
11 enrollees (at the time of enrollment and during an annual open season as  
12 provided under subsection (c)) the option of health insurance coverage which  
13 provides for coverage of such services which are not furnished through  
14 health care professionals and providers who are members of such a network  
15 unless enrollees are offered such non-network coverage through another  
16 health insurance issuer.

17 “(b) ADDITIONAL COSTS.—The amount of any additional premium  
18 charged by the health insurance issuer for the additional cost of the creation  
19 and maintenance of the option described in subsection (a) and the amount  
20 of any additional cost sharing imposed under such option shall be borne by  
21 the enrollee unless it is paid by the health plan sponsor through agreement  
22 with the health insurance issuer.

23 “(c) OPEN SEASON.—An enrollee may change to the offering provided  
24 under this section only during a time period determined by the health insur-  
25 ance issuer. Such time period shall occur at least annually.

#### 26 **“SEC. 2812. CHOICE OF HEALTH CARE PROFESSIONAL.**

27 “(a) PRIMARY CARE.—If a group health plan, or a health insurance  
28 issuer that offers health insurance coverage, requires or provides for des-  
29 ignation by a participant, beneficiary, or enrollee of a participating primary  
30 care provider, then the plan or issuer shall permit each participant, bene-  
31 ficiary, and enrollee to designate any participating primary care provider  
32 who is available to accept such individual.

33 “(b) SPECIALISTS.—A group health plan and a health insurance issuer  
34 that offers health insurance coverage shall permit each participant, bene-  
35 ficiary, or enrollee to receive medically necessary or appropriate specialty  
36 care, pursuant to appropriate referral procedures, from any qualified par-  
37 ticipating health care professional who is available to accept such individual  
38 for such care.

#### 39 **“SEC. 2813. ACCESS TO EMERGENCY CARE.**

40 “(a) COVERAGE OF EMERGENCY SERVICES.—

## 22

1           “(1) IN GENERAL.—If a group health plan, or health insurance  
2 coverage offered by a health insurance issuer, provides or covers any  
3 benefits with respect to services in an emergency department of a hos-  
4 pital, the plan or issuer shall cover emergency services (as defined in  
5 paragraph (2)(B))—

6           “(A) without the need for any prior authorization determina-  
7 tion;

8           “(B) whether the health care provider furnishing such serv-  
9 ices is a participating provider with respect to such services;

10           “(C) in a manner so that, if such services are provided to a  
11 participant, beneficiary, or enrollee—

12           “(i) by a nonparticipating health care provider with or  
13 without prior authorization, or

14           “(ii) by a participating health care provider without prior  
15 authorization,

16 the participant, beneficiary, or enrollee is not liable for amounts  
17 that exceed the amounts of liability that would be incurred if the  
18 services were provided by a participating health care provider with  
19 prior authorization; and

20           “(D) without regard to any other term or condition of such  
21 coverage (other than exclusion or coordination of benefits, or an  
22 affiliation or waiting period, permitted under section 2701 of the  
23 Public Health Service Act, section 701 of the Employee Retire-  
24 ment Income Security Act of 1974, or section 9801 of the Internal  
25 Revenue Code of 1986, and other than applicable cost-sharing).

26           “(2) DEFINITIONS.—In this section:

27           “(A) EMERGENCY MEDICAL CONDITION.—The term ‘emer-  
28 gency medical condition’ means—

29           “(i) a medical condition manifesting itself by acute  
30 symptoms of sufficient severity (including severe pain) such  
31 that a prudent layperson, who possesses an average knowl-  
32 edge of health and medicine, could reasonably expect the ab-  
33 sence of immediate medical attention to result in a condition  
34 described in clause (i), (ii), or (iii) of section 1867(e)(1)(A)  
35 of the Social Security Act; and

36           “(ii) a medical condition manifesting itself in a neonate  
37 by acute symptoms of sufficient severity (including severe  
38 pain) such that a prudent health care professional could rea-  
39 sonably expect the absence of immediate medical attention to  
40 result in a condition described in clause (i), (ii), or (iii) of sec-  
41 tion 1867(e)(1)(A) of the Social Security Act.

## 23

1 “(B) EMERGENCY SERVICES.—The term ‘emergency services’  
2 means—

3 “(i) with respect to an emergency medical condition de-  
4 scribed in subparagraph (A)(i)—

5 “(I) a medical screening examination (as required  
6 under section 1867 of the Social Security Act) that is  
7 within the capability of the emergency department of a  
8 hospital, including ancillary services routinely available  
9 to the emergency department to evaluate such emergency  
10 medical condition, and

11 “(II) within the capabilities of the staff and facili-  
12 ties available at the hospital, such further medical exam-  
13 ination and treatment as are required under section  
14 1867 of such Act to stabilize the patient; or

15 “(ii) with respect to an emergency medical condition de-  
16 scribed in subparagraph (A)(ii), medical treatment for such  
17 condition rendered by a health care provider in a hospital to  
18 a neonate, including available hospital ancillary services in re-  
19 sponse to an urgent request of a health care professional and  
20 to the extent necessary to stabilize the neonate.

21 “(C) STABILIZE.—The term ‘to stabilize’ means, with respect  
22 to an emergency medical condition, to provide such medical treat-  
23 ment of the condition as may be necessary to assure, within rea-  
24 sonable medical probability, that no material deterioration of the  
25 condition is likely to result from or occur during the transfer of  
26 the individual from a facility.

27 “(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STA-  
28 BILIZATION CARE.—If benefits are available under a group health plan, or  
29 under health insurance coverage offered by a health insurance issuer, with  
30 respect to maintenance care or post-stabilization care covered under the  
31 guidelines established under section 1852(d)(2) of the Social Security Act,  
32 the plan or issuer shall provide for reimbursement with respect to such serv-  
33 ices provided to a participant, beneficiary, or enrollee other than through  
34 a participating health care provider in a manner consistent with subsection  
35 (a)(1)(C) (and shall otherwise comply with such guidelines).

36 “(c) COVERAGE OF EMERGENCY AMBULANCE SERVICES.—

37 “(1) IN GENERAL.—If a group health plan, or health insurance  
38 coverage provided by a health insurance issuer, provides any benefits  
39 with respect to ambulance services and emergency services, the plan or  
40 issuer shall cover emergency ambulance services (as defined in para-  
41 graph (2))) furnished under the plan or coverage under the same terms

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1 and conditions under subparagraphs (A) through (D) of subsection  
2 (a)(1) under which coverage is provided for emergency services.

3 “(2) EMERGENCY AMBULANCE SERVICES.—For purposes of this  
4 subsection, the term ‘emergency ambulance services’ means ambulance  
5 services (as defined for purposes of section 1861(s)(7) of the Social Se-  
6 curity Act) furnished to transport an individual who has an emergency  
7 medical condition (as defined in subsection (a)(2)(A)) to a hospital for  
8 the receipt of emergency services (as defined in subsection (a)(2)(B))  
9 in a case in which the emergency services are covered under the plan  
10 or coverage pursuant to subsection (a)(1) and a prudent layperson,  
11 with an average knowledge of health and medicine, could reasonably ex-  
12 pect that the absence of such transport would result in placing the  
13 health of the individual in serious jeopardy, serious impairment of bod-  
14 ily function, or serious dysfunction of any bodily organ or part.

15 **“SEC. 2814. ACCESS TO SPECIALTY CARE.**

16 “(a) SPECIALTY CARE FOR COVERED SERVICES.—

17 “(1) IN GENERAL.—If—

18 “(A) an individual is a participant or beneficiary under a  
19 group health plan or an enrollee who is covered under health in-  
20 surance coverage offered by a health insurance issuer,

21 “(B) the individual has a condition or disease of sufficient se-  
22 riousness and complexity to require treatment by a specialist or  
23 the individual requires physician pathology services, and

24 “(C) benefits for such treatment or services are provided  
25 under the plan or coverage,

26 the plan or issuer shall make or provide for a referral to a specialist  
27 who is available and accessible (consistent with standards developed  
28 under section 2818) to provide the treatment for such condition or dis-  
29 ease or to provide such services.

30 “(2) SPECIALIST DEFINED.—For purposes of this subsection, the  
31 term ‘specialist’ means, with respect to a condition or services, a health  
32 care practitioner, facility, or center or physician pathologist that has  
33 adequate expertise through appropriate training and experience (includ-  
34 ing, in the case of a child, appropriate pediatric expertise and in the  
35 case of a pregnant woman, appropriate obstetrical expertise) to provide  
36 high quality care in treating the condition or to provide physician pa-  
37 thology services.

38 “(3) CARE UNDER REFERRAL.—A group health plan or health in-  
39 surance issuer may require that the care provided to an individual pur-  
40 suant to such referral under paragraph (1) with respect to treatment  
41 be—



## 25

1           “(A) pursuant to a treatment plan, only if the treatment plan  
2           is developed by the specialist and approved by the plan or issuer,  
3           in consultation with the designated primary care provider or spe-  
4           cialist and the individual (or the individual’s designee), and

5           “(B) in accordance with applicable quality assurance and uti-  
6           lization review standards of the plan or issuer.

7           Nothing in this subsection shall be construed as preventing such a  
8           treatment plan for an individual from requiring a specialist to provide  
9           the primary care provider with regular updates on the specialty care  
10          provided, as well as all necessary medical information.

11          “(4) REFERRALS TO PARTICIPATING PROVIDERS.—A group health  
12          plan or health insurance issuer is not required under paragraph (1) to  
13          provide for a referral to a specialist that is not a participating provider,  
14          unless the plan or issuer does not have a specialist that is available and  
15          accessible to treat the individual’s condition or provide physician pa-  
16          thology services and that is a participating provider with respect to  
17          such treatment or services.

18          “(5) REFERRALS TO NONPARTICIPATING PROVIDERS.—In a case  
19          in which a referral of an individual to a nonparticipating specialist is  
20          required under paragraph (1), the group health plan or health insur-  
21          ance issuer shall provide the individual the option of at least three non-  
22          participating specialists.

23          “(6) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan  
24          or issuer refers an individual to a nonparticipating specialist pursuant  
25          to paragraph (1), services provided pursuant to the approved treatment  
26          plan (if any) shall be provided at no additional cost to the individual  
27          beyond what the individual would otherwise pay for services received  
28          by such a specialist that is a participating provider.

29          “(b) SPECIALISTS AS GATEKEEPER FOR TREATMENT OF ONGOING  
30          SPECIAL CONDITIONS.—

31          “(1) IN GENERAL.—A group health plan, or a health insurance  
32          issuer, in connection with the provision of health insurance coverage,  
33          shall have a procedure by which an individual who is a participant, ben-  
34          eficiary, or enrollee and who has an ongoing special condition (as de-  
35          fined in paragraph (3)) may request and receive a referral to a spe-  
36          cialist for such condition who shall be responsible for and capable of  
37          providing and coordinating the individual’s care with respect to the  
38          condition. Under such procedures if such an individual’s care would  
39          most appropriately be coordinated by such a specialist, such plan or  
40          issuer shall refer the individual to such specialist.

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1           “(2) TREATMENT FOR RELATED REFERRALS.—Such specialists  
2       shall be permitted to treat the individual without a referral from the  
3       individual’s primary care provider and may authorize such referrals,  
4       procedures, tests, and other medical services as the individual’s primary  
5       care provider would otherwise be permitted to provide or authorize,  
6       subject to the terms of the treatment (referred to in subsection  
7       (a)(3)(A)) with respect to the ongoing special condition.

8           “(3) ONGOING SPECIAL CONDITION DEFINED.—In this subsection,  
9       the term ‘ongoing special condition’ means a condition or disease  
10      that—

11           “(A) is life-threatening, degenerative, or disabling, and

12           “(B) requires specialized medical care over a prolonged period  
13      of time.

14           “(4) TERMS OF REFERRAL.—The provisions of paragraphs (3)  
15       through (5) of subsection (a) apply with respect to referrals under  
16       paragraph (1) of this subsection in the same manner as they apply to  
17       referrals under subsection (a)(1).

18           “(5) CONSTRUCTION.—Nothing in this subsection shall be con-  
19       strued as preventing an individual who is a participant, beneficiary, or  
20       enrollee and who has an ongoing special condition from having the indi-  
21       vidual’s primary care physician assume the responsibilities for pro-  
22       viding and coordinating care described in paragraph (1).

23           “(c) STANDING REFERRALS.—

24           “(1) IN GENERAL.—A group health plan, and a health insurance  
25       issuer in connection with the provision of health insurance coverage,  
26       shall have a procedure by which an individual who is a participant, ben-  
27       eficiary, or enrollee and who has a condition that requires ongoing care  
28       from a specialist may receive a standing referral to such specialist for  
29       treatment of such condition. If the plan or issuer, or if the primary  
30       care provider in consultation with the medical director of the plan or  
31       issuer and the specialist (if any), determines that such a standing re-  
32       ferral is appropriate, the plan or issuer shall make such a referral to  
33       such a specialist if the individual so desires.

34           “(2) TERMS OF REFERRAL.—The provisions of paragraphs (3)  
35       through (5) of subsection (a) apply with respect to referrals under  
36       paragraph (1) of this subsection in the same manner as they apply to  
37       referrals under subsection (a)(1).

38       **“SEC. 2815. ACCESS TO OBSTETRICAL AND GYNECOLOGICAL CARE.**

39           “(a) IN GENERAL.—If a group health plan, or a health insurance  
40       issuer in connection with the provision of health insurance coverage, re-

quires or provides for a participant, beneficiary, or enrollee to designate a participating primary care health care professional, the plan or issuer—

“(1) may not require authorization or a referral by the individual’s primary care health care professional or otherwise for covered gynecological care (including preventive women’s health examinations) or for covered pregnancy-related services provided by a participating physician (including a family practice physician) who specializes or is trained and experienced in gynecology or obstetrics, respectively, to the extent such care is otherwise covered; and

“(2) shall treat the ordering of other gynecological or obstetrical care by such a participating physician as the authorization of the primary care health care professional with respect to such care under the plan or coverage.

“(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed to—

“(1) waive any exclusions of coverage under the terms of the plan with respect to coverage of gynecological or obstetrical care;

“(2) preclude the group health plan or health insurance issuer involved from requiring that the gynecologist or obstetrician notify the primary care health care professional or the plan of treatment decisions; or

“(3) prevent a plan or issuer from offering, in addition to physicians described in subsection (a)(1), non-physician health care professionals who are trained and experienced in gynecology or obstetrics.

**“SEC. 2816. ACCESS TO PEDIATRIC CARE.**

“(a) PEDIATRIC CARE.—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, requires or provides for an enrollee to designate a participating primary care provider for a child of such enrollee, the plan or issuer shall permit the enrollee to designate a physician (including a family practice physician) who specializes or is trained and experienced in pediatrics as the child’s primary care provider.

“(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed to waive any exclusions of coverage under the terms of the plan with respect to coverage of pediatric care.

**“SEC. 2817. CONTINUITY OF CARE.**

“(a) IN GENERAL.—

“(1) TERMINATION OF PROVIDER.—If a contract between a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, and a health care provider is terminated (as defined in paragraph (3)(B)), or benefits or coverage pro-

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1 vided by a health care provider are terminated because of a change in  
2 the terms of provider participation in a group health plan, and an indi-  
3 vidual who is a participant, beneficiary, or enrollee in the plan or cov-  
4 erage is undergoing treatment from the provider for an ongoing special  
5 condition (as defined in paragraph (3)(A)) at the time of such termi-  
6 nation, the plan or issuer shall—

7 “(A) notify the individual on a timely basis of such termi-  
8 nation and of the right to elect continuation of coverage of treat-  
9 ment by the provider under this section; and

10 “(B) subject to subsection (c), permit the individual to elect  
11 to continue to be covered with respect to treatment by the provider  
12 of such condition during a transitional period (provided under sub-  
13 section (b)).

14 “(2) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH  
15 INSURANCE ISSUER.—If a contract for the provision of health insur-  
16 ance coverage between a group health plan and a health insurance  
17 issuer is terminated and, as a result of such termination, coverage of  
18 services of a health care provider is terminated with respect to an indi-  
19 vidual, the provisions of paragraph (1) (and the succeeding provisions  
20 of this section) shall apply under the plan in the same manner as if  
21 there had been a contract between the plan and the provider that had  
22 been terminated, but only with respect to benefits that are covered  
23 under the plan after the contract termination.

24 “(3) DEFINITIONS.—For purposes of this section:

25 “(A) ONGOING SPECIAL CONDITION.—The term ‘ongoing spe-  
26 cial condition’ has the meaning given such term in section  
27 2814(b)(3), and also includes pregnancy.

28 “(B) TERMINATION.—The term ‘terminated’ includes, with  
29 respect to a contract, the expiration or nonrenewal of the contract,  
30 but does not include a termination of the contract by the plan or  
31 issuer for failure to meet applicable quality standards or for fraud.

32 “(b) TRANSITIONAL PERIOD.—

33 “(1) IN GENERAL.—Except as provided in paragraphs (2) through  
34 (4), the transitional period under this subsection shall extend up to 90  
35 days (as determined by the treating health care professional) after the  
36 date of the notice described in subsection (a)(1)(A) of the provider’s  
37 termination.

38 “(2) SCHEDULED SURGERY AND ORGAN TRANSPLANTATION.—If  
39 surgery or organ transplantation was scheduled for an individual before  
40 the date of the announcement of the termination of the provider status  
41 under subsection (a)(1)(A) or if the individual on such date was on an

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1 established waiting list or otherwise scheduled to have such surgery or  
2 transplantation, the transitional period under this subsection with re-  
3 spect to the surgery or transplantation shall extend beyond the period  
4 under paragraph (1) and until the date of discharge of the individual  
5 after completion of the surgery or transplantation.

6 “(3) PREGNANCY.—If—

7 “(A) a participant, beneficiary, or enrollee was determined to  
8 be pregnant at the time of a provider’s termination of participa-  
9 tion, and

10 “(B) the provider was treating the pregnancy before date of  
11 the termination,

12 the transitional period under this subsection with respect to provider’s  
13 treatment of the pregnancy shall extend through the provision of post-  
14 partum care directly related to the delivery.

15 “(4) TERMINAL ILLNESS.—If—

16 “(A) a participant, beneficiary, or enrollee was determined to  
17 be terminally ill (as determined under section 1861(dd)(3)(A) of  
18 the Social Security Act) at the time of a provider’s termination of  
19 participation, and

20 “(B) the provider was treating the terminal illness before the  
21 date of termination,

22 the transitional period under this subsection shall extend for the re-  
23 mainder of the individual’s life for care directly related to the treat-  
24 ment of the terminal illness or its medical manifestations.

25 “(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan or  
26 health insurance issuer may condition coverage of continued treatment by  
27 a provider under subsection (a)(1)(B) upon the individual notifying the plan  
28 of the election of continued coverage and upon the provider agreeing to the  
29 following terms and conditions:

30 “(1) The provider agrees to accept reimbursement from the plan  
31 or issuer and individual involved (with respect to cost-sharing) at the  
32 rates applicable prior to the start of the transitional period as payment  
33 in full (or, in the case described in subsection (a)(2), at the rates appli-  
34 cable under the replacement plan or issuer after the date of the termi-  
35 nation of the contract with the health insurance issuer) and not to im-  
36 pose cost-sharing with respect to the individual in an amount that  
37 would exceed the cost-sharing that could have been imposed if the con-  
38 tract referred to in subsection (a)(1) had not been terminated.

39 “(2) The provider agrees to adhere to the quality assurance stand-  
40 ards of the plan or issuer responsible for payment under paragraph (1)

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1 and to provide to such plan or issuer necessary medical information re-  
2 lated to the care provided.

3 “(3) The provider agrees otherwise to adhere to such plan’s or  
4 issuer’s policies and procedures, including procedures regarding refer-  
5 rals and obtaining prior authorization and providing services pursuant  
6 to a treatment plan (if any) approved by the plan or issuer.

7 “(d) CONSTRUCTION.—Nothing in this section shall be construed to re-  
8 quire the coverage of benefits which would not have been covered if the pro-  
9 vider involved remained a participating provider.

10 **“SEC. 2818. NETWORK ADEQUACY.**

11 “(a) REQUIREMENT.—A group health plan, and a health insurance  
12 issuer providing health insurance coverage, shall meet such standards for  
13 network adequacy as are established by law pursuant to this section.

14 “(b) DEVELOPMENT OF STANDARDS.—

15 “(1) ESTABLISHMENT OF PANEL.—There is established a panel to  
16 be known as the Health Care Panel to Establish Network Adequacy  
17 Standards (in this section referred to as the ‘Panel’).

18 “(2) DUTIES OF PANEL.—The Panel shall devise standards for  
19 group health plans and health insurance issuers that offer health insur-  
20 ance coverage to ensure that—

21 “(A) participants, beneficiaries, and enrollees have access to  
22 a sufficient number, mix, and distribution of health care profes-  
23 sionals and providers; and

24 “(B) covered items and services are available and accessible  
25 to each participant, beneficiary, and enrollee—

26 “(i) in the service area of the plan or issuer;

27 “(ii) at a variety of sites of service;

28 “(iii) with reasonable promptness (including reasonable  
29 hours of operation and after hours services);

30 “(iv) with reasonable proximity to the residences or  
31 workplaces of enrollees; and

32 “(v) in a manner that takes into account the diverse  
33 needs of enrollees and reasonably assures continuity of care.

34 “(c) MEMBERSHIP.—

35 “(1) SIZE AND COMPOSITION.—The Panel shall be composed of 15  
36 members. The Secretary of Health and Human Services, the Majority  
37 Leader of the Senate, and the Speaker of House of Representatives  
38 shall each appoint 1 member from representatives of private insurance  
39 organizations, consumer groups, State insurance commissioners, State  
40 medical societies, and State medical specialty societies.

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1           “(2) TERMS OF APPOINTMENT.—The members of the Panel shall  
2           serve for the life of the Panel.

3           “(3) VACANCIES.—A vacancy in the Panel shall not affect the  
4           power of the remaining members to execute the duties of the Panel,  
5           but any such vacancy shall be filled in the same manner in which the  
6           original appointment was made.

7           “(d) PROCEDURES.—

8           “(1) MEETINGS.—The Panel shall meet at the call of a majority  
9           of its members.

10          “(2) FIRST MEETING.—The Panel shall convene not later than 60  
11          days after the date of the enactment of the Health Care Quality and  
12          Choice Act of 1999.

13          “(3) QUORUM.—A quorum shall consist of a majority of the mem-  
14          bers of the Panel.

15          “(4) HEARINGS.—For the purpose of carrying out its duties, the  
16          Panel may hold such hearings and undertake such other activities as  
17          the Panel determines to be necessary to carry out its duties.

18          “(e) ADMINISTRATION.—

19          “(1) COMPENSATION.—Except as provided in paragraph (1),  
20          members of the Panel shall receive no additional pay, allowances, or  
21          benefits by reason of their service on the Panel.

22          “(2) TRAVEL EXPENSES AND PER DIEM.—Each member of the  
23          Panel who is not an officer or employee of the Federal Government  
24          shall receive travel expenses and per diem in lieu of subsistence in ac-  
25          cordance with sections 5702 and 5703 of title 5, United States Code.

26          “(3) CONTRACT AUTHORITY.—The Panel may contract with and  
27          compensate government and private agencies or persons for items and  
28          services, without regard to section 3709 of the Revised Statutes (41  
29          U.S.C. 5).

30          “(4) USE OF MAILS.—The Panel may use the United States mails  
31          in the same manner and under the same conditions as Federal agencies  
32          and shall, for purposes of the frank, be considered a commission of  
33          Congress as described in section 3215 of title 39, United States Code.

34          “(5) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of  
35          the Panel, the Secretary of Health and Human Services shall provide  
36          to the Panel on a reimbursable basis such administrative support serv-  
37          ices as the Panel may request.

38          “(f) REPORT AND ESTABLISHMENT OF STANDARDS.—Not later than  
39          2 years after the first meeting, the Panel shall submit a report to Congress  
40          and the Secretary of Health and Human Services detailing the standards  
41          devised under subsection (b) and recommendations regarding the implemen-

1 tation of such standards. Such standards shall take effect to the extent pro-  
2 vided by Federal law enacted after the date of the submission of such re-  
3 port.

4 “(g) TERMINATION.—The Panel shall terminate on the day after sub-  
5 mitting its report to the Secretary of Health and Human Services under  
6 subsection (f).

7 **“SEC. 2819. ACCESS TO EXPERIMENTAL OR INVESTIGATIONAL PRE-**  
8 **SCRIPTION DRUGS.**

9 “No use of a prescription drug or medical device shall be considered  
10 experimental or investigational under a group health plan or under health  
11 insurance coverage provided by a health insurance issuer if such use is in-  
12 cluded in the labeling authorized by the U.S. Food and Drug Administra-  
13 tion under section 505, 513 or 515 of the Federal Food, Drug, and Cos-  
14 metic Act (21 U.S.C. 355) or under section 351 of the Public Health Ser-  
15 vice Act (42 U.S.C. 262), unless such use is demonstrated to be unsafe or  
16 ineffective.

17 **“SEC. 2820. COVERAGE FOR INDIVIDUALS PARTICIPATING IN AP-**  
18 **PROVED CANCER CLINICAL TRIALS.**

19 “(a) COVERAGE.—

20 “(1) IN GENERAL.—If a group health plan (or a health insurance  
21 issuer offering health insurance coverage) provides coverage to a quali-  
22 fied individual (as defined in subsection (b)), the plan or issuer—

23 “(A) may not deny the individual participation in the clinical  
24 trial referred to in subsection (b)(2);

25 “(B) subject to subsections (b), (c), and (d), may not deny  
26 (or limit or impose additional conditions on) the coverage of rou-  
27 tine patient costs for items and services furnished in connection  
28 with participation in the trial; and

29 “(C) may not discriminate against the individual on the basis  
30 of the individual’s participation in such trial.

31 “(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph  
32 (1)(B), routine patient costs do not include the cost of the tests or  
33 measurements conducted primarily for the purpose of the clinical trial  
34 involved.

35 “(3) USE OF IN-NETWORK PROVIDERS.—If one or more partici-  
36 pating providers is participating in a clinical trial, nothing in para-  
37 graph (1) shall be construed as preventing a plan or issuer from requir-  
38 ing that a qualified individual participate in the trial through such a  
39 participating provider if the provider will accept the individual as a par-  
40 ticipant in the trial.

41 “(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection  
42 (a), the term ‘qualified individual’ means an individual who is a participant



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1 or beneficiary in a group health plan or an enrollee in health insurance cov-  
2 erage and who meets the following conditions:

3 “(1)(A) The individual has been diagnosed with cancer.

4 “(B) The individual is eligible to participate in an approved clin-  
5 ical trial according to the trial protocol with respect to treatment of  
6 such illness.

7 “(C) The individual’s participation in the trial offers meaningful  
8 potential for significant clinical benefit for the individual.

9 “(2) Either—

10 “(A) the referring physician is a participating health care  
11 professional and has concluded that the individual’s participation  
12 in such trial would be appropriate based upon the individual meet-  
13 ing the conditions described in paragraph (1); or

14 “(B) the individual provides medical and scientific informa-  
15 tion establishing that the individual’s participation in such trial  
16 would be appropriate based upon the individual meeting the condi-  
17 tions described in paragraph (1).

18 “(c) PAYMENT.—

19 “(1) IN GENERAL.—Under this section a group health plan (or  
20 health insurance issuer offering health insurance) shall provide for pay-  
21 ment for routine patient costs described in subsection (a)(2) but is not  
22 required to pay for costs of items and services that are reasonably ex-  
23 pected to be paid for by the sponsors of an approved clinical trial.

24 “(2) ROUTINE PATIENT CARE COSTS.—For purposes of this  
25 section—

26 “(A) IN GENERAL.—The term ‘routine patient care costs’ in-  
27 cludes the costs associated with the provision of items and services  
28 that—

29 “(i) would otherwise be covered under the group health  
30 plan or health insurance coverage if such items and services  
31 were not provided in connection with an approved clinical  
32 trial program; and

33 “(ii) are furnished according to the protocol of an ap-  
34 proved clinical trial program.

35 “(B) EXCLUSION.—Such term does include the costs associ-  
36 ated with the provision of—

37 “(i) an investigational drug or device, unless the Sec-  
38 retary has authorized the manufacturer of such drug or de-  
39 vice to charge for such drug or device; or

40 “(ii) any item or service supplied without charge by the  
41 sponsor of the approved clinical trial program.

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1           “(3) PAYMENT RATE.—In the case of covered items and services  
2       provided by—

3           “(A) a participating provider, the payment rate shall be at  
4       the agreed upon rate, or

5           “(B) a nonparticipating provider, the payment rate shall be  
6       at the rate the plan or issuer would normally pay for comparable  
7       items or services under subparagraph (A).

8           “(d) APPROVED CLINICAL TRIAL DEFINED.—In this section, the term  
9       ‘approved clinical trial’ means a cancer clinical research study or cancer  
10      clinical investigation approved by an Institutional Review Board.

11          “(e) CONSTRUCTION.—Nothing in this section shall be construed to  
12      limit a plan’s or issuer’s coverage with respect to clinical trials.

13          “(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBIL-  
14      ITIES OF FIDUCIARIES.—

15          “(1) IN GENERAL.—For purposes of this section, insofar as a  
16      group health plan provides benefits in the form of health insurance cov-  
17      erage through a health insurance issuer, the plan shall be treated as  
18      meeting the requirements of this section with respect to such benefits  
19      and not be considered as failing to meet such requirements because of  
20      a failure of the issuer to meet such requirements so long as the plan  
21      sponsor or its representatives did not cause such failure by the issuer.

22          “(2) CONSTRUCTION.—Nothing in this section shall be construed  
23      to affect or modify the responsibilities of the fiduciaries of a group  
24      health plan under part 4 of subtitle B of the Employee Retirement In-  
25      come Security Act of 1974.

26          “(g) STUDY AND REPORT.—

27          “(1) STUDY.—The Secretary of Health and Human Services, in  
28      consultation with the Secretary and the Secretary of the Treasury,  
29      shall analyze cancer clinical research and its cost implications for man-  
30      aged care, including differentiation in—

31              “(A) the cost of patient care in trials versus standard care;

32              “(B) the cost effectiveness achieved in different sites of serv-  
33      ice;

34              “(C) research outcomes;

35              “(D) volume of research subjects available in different sites  
36      of service;

37              “(E) access to research sites and clinical trials by cancer pa-  
38      tients;

39              “(F) patient cost sharing or copayment costs realized in dif-  
40      ferent sites of service;

41              “(G) health outcomes experienced in different sites of service;

1 “(H) long term health care services and costs experienced in  
2 different sites of service;

3 “(I) morbidity and mortality experienced in different sites of  
4 service; and

5 “(J) patient satisfaction and preference of sites of service.

6 “(2) REPORT TO CONGRESS.—Not later than January 1, 2005,  
7 the Secretary of Health and Human Services shall submit a report to  
8 Congress that contains—

9 “(A) an assessment of any incremental cost to group health  
10 plans and health insurance issuers resulting from the provisions of  
11 this section;

12 “(B) a projection of expenditures to such plans and issuers  
13 resulting from this section;

14 “(C) an assessment of any impact on premiums resulting  
15 from this section; and

16 “(D) recommendations regarding action on other diseases.

17 **“Subtitle C—Access to Information**

18 **“SEC. 2821. PATIENT ACCESS TO INFORMATION.**

19 “(a) DISCLOSURE REQUIREMENT.—

20 “(1) GROUP HEALTH PLANS.—A group health plan shall—

21 “(A) provide to participants and beneficiaries at the time of  
22 initial coverage under the plan (or the effective date of this sec-  
23 tion, in the case of individuals who are participants or bene-  
24 ficiaries as of such date), and at least annually thereafter, the in-  
25 formation described in subsection (b);

26 “(B) provide to participants and beneficiaries, within a rea-  
27 sonable period (as specified by the Secretary) before or after the  
28 date of significant changes in the information described in sub-  
29 section (b), information on such significant changes; and

30 “(C) upon request, make available to participants and bene-  
31 ficiaries, the Secretary, and prospective participants and bene-  
32 ficiaries, the information described in subsection (b) or (c).

33 The plan may charge a reasonable fee for provision in printed form of  
34 any of the information described in subsection (b) or (c) more than  
35 once during any plan year.

36 “(2) HEALTH INSURANCE ISSUERS.—A health insurance issuer in  
37 connection with the provision of health insurance coverage shall—

38 “(A) provide to individuals enrolled under such coverage at  
39 the time of enrollment, and at least annually thereafter, the infor-  
40 mation described in subsection (b);

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1 “(B) provide to enrollees, within a reasonable period (as spec-  
2 ified by the Secretary) before or after the date of significant  
3 changes in the information described in subsection (b), informa-  
4 tion in printed form on such significant changes; and

5 “(C) upon request, make available to the Secretary, to indi-  
6 viduals who are prospective enrollees, and to the public the infor-  
7 mation described in subsection (b) or (c).

8 “(b) INFORMATION PROVIDED.—The information described in this sub-  
9 section with respect to a group health plan or health insurance coverage of-  
10 fered by a health insurance issuer shall be provided to a participant, bene-  
11 ficiary, or enrollee free of charge at least once a year and includes the fol-  
12 lowing:

13 “(1) SERVICE AREA.—The service area of the plan or issuer.

14 “(2) BENEFITS.—Benefits offered under the plan or coverage,  
15 including—

16 “(A) those that are covered benefits “(all of which shall be  
17 referred to by such relevant CPT and DRG codes as are avail-  
18 able), limits and conditions on such benefits, and those benefits  
19 that are explicitly excluded from coverage (all of which shall be re-  
20 ferred to by such relevant CPT and DRG codes as are available);

21 “(B) cost sharing, such as deductibles, coinsurance, and co-  
22 payment amounts, including any liability for balance billing, any  
23 maximum limitations on out of pocket expenses, and the maximum  
24 out of pocket costs for services that are provided by nonpartici-  
25 pating providers or that are furnished without meeting the appli-  
26 cable utilization review requirements;

27 “(C) the extent to which benefits may be obtained from non-  
28 participating providers;

29 “(D) the extent to which a participant, beneficiary, or en-  
30 rollee may select from among participating providers and the types  
31 of providers participating in the plan or issuer network;

32 “(E) process for determining experimental coverage; and

33 “(F) use of a prescription drug formulary.

34 “(3) ACCESS.—A description of the following:

35 “(A) The number, mix, and distribution of providers under  
36 the plan or coverage.

37 “(B) Out-of-network coverage (if any) provided by the plan  
38 or coverage.

39 “(C) Any point-of-service option (including any supplemental  
40 premium or cost-sharing for such option).

1 “(D) The procedures for participants, beneficiaries, and en-  
2 rollees to select, access, and change participating primary and spe-  
3 cialty providers.

4 “(E) The rights and procedures for obtaining referrals (in-  
5 cluding standing referrals) to participating and nonparticipating  
6 providers.

7 “(F) The name, address, and telephone number of partici-  
8 pating health care providers and an indication of whether each  
9 such provider is available to accept new patients.

10 “(G) Any limitations imposed on the selection of qualifying  
11 participating health care providers, including any limitations im-  
12 posed under section 2812(b)(2).

13 “(4) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by  
14 the plan or issuer.

15 “(5) EMERGENCY COVERAGE.—Coverage of emergency services,  
16 including—

17 “(A) the appropriate use of emergency services, including use  
18 of the 911 telephone system or its local equivalent in emergency  
19 situations and an explanation of what constitutes an emergency  
20 situation;

21 “(B) the process and procedures of the plan or issuer for ob-  
22 taining emergency services; and

23 “(C) the locations of (i) emergency departments, and (ii)  
24 other settings, in which plan physicians and hospitals provide  
25 emergency services and post-stabilization care.

26 “(6) PRIOR AUTHORIZATION RULES.—Rules regarding prior au-  
27 thorization or other review requirements that could result in noncov-  
28 erage or nonpayment.

29 “(7) GRIEVANCE AND APPEALS PROCEDURES.—All appeal or  
30 grievance rights and procedures under the plan or coverage, including  
31 the method for filing grievances and the time frames and circumstances  
32 for acting on grievances and appeals, who is the applicable authority  
33 with respect to the plan or issuer.

34 “(8) ACCOUNTABILITY.—A description of the legal recourse op-  
35 tions available for participants and beneficiaries under the plan  
36 including—

37 “(A) the preemption that applies under section 514 of the  
38 Employee Retirement Income Security Act of 1974 (29 U.S.C.  
39 1144) to certain actions arising out of the provision of health ben-  
40 efits; and

1 “(B) the extent to which coverage decisions made by the plan  
2 are subject to internal review or any external review and the prop-  
3 er time frames under

4 “(9) QUALITY ASSURANCE.—Any information made public by an  
5 accrediting organization in the process of accreditation of the plan or  
6 issuer or any additional quality indicators the plan or issuer makes  
7 available.

8 “(10) INFORMATION ON ISSUER.—Notice of appropriate mailing  
9 addresses and telephone numbers to be used by participants, bene-  
10 ficiaries, and enrollees in seeking information or authorization for  
11 treatment.

12 “(11) AVAILABILITY OF INFORMATION ON REQUEST.—Notice that  
13 the information described in subsection (c) is available upon request.

14 “(c) INFORMATION MADE AVAILABLE UPON REQUEST.—The informa-  
15 tion described in this subsection is the following:

16 “(1) UTILIZATION REVIEW ACTIVITIES.—A description of proce-  
17 dures used and requirements (including circumstances, time frames,  
18 and appeal rights) under any utilization review program under section  
19 2801.

20 “(2) GRIEVANCE AND APPEALS INFORMATION.—Information on  
21 the number of grievances and appeals and on the disposition in the ag-  
22 gregate of such matters.

23 “(3) FORMULARY RESTRICTIONS.—A description of the nature of  
24 any drug formula restrictions.

25 “(4) PARTICIPATING PROVIDER LIST.—A list of current partici-  
26 pating health care providers.

27 “(d) CONSTRUCTION.—Nothing in this section shall be construed as re-  
28 quiring public disclosure of individual contracts or financial arrangements  
29 between a group health plan or health insurance issuer and any provider.

## 30 **“Subtitle D—Protecting the Doctor-Patient** 31 **Relationship**

### 32 **“SEC. 2831. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL** 33 **COMMUNICATIONS.**

34 “(a) GENERAL RULE.—The provisions of any contract or agreement,  
35 or the operation of any contract or agreement, between a group health plan  
36 or health insurance issuer in relation to health insurance coverage (including  
37 any partnership, association, or other organization that enters into or ad-  
38 ministers such a contract or agreement) and a health care provider (or  
39 group of health care providers) shall not prohibit or otherwise restrict a  
40 health care professional from advising such a participant, beneficiary, or en-  
41 rollee who is a patient of the professional about the health status of the

1 individual or medical care or treatment for the individual's condition or dis-  
2 ease, regardless of whether benefits for such care or treatment are provided  
3 under the plan or coverage, if the professional is acting within the lawful  
4 scope of practice.

5 “(b) NULLIFICATION.—Any contract provision or agreement that re-  
6 stricts or prohibits medical communications in violation of subsection (a)  
7 shall be null and void.

8 **“SEC. 2832. PROHIBITION OF DISCRIMINATION AGAINST PROVIDERS**  
9 **BASED ON LICENSURE.**

10 “(a) IN GENERAL.—A group health plan and a health insurance issuer  
11 offering health insurance coverage shall not discriminate with respect to  
12 participation or indemnification as to any provider who is acting within the  
13 scope of the provider's license or certification under applicable State law,  
14 solely on the basis of such license or certification.

15 “(b) CONSTRUCTION.—Subsection (a) shall not be construed—

16 “(1) as requiring the coverage under a group health plan or health  
17 insurance coverage of particular benefits or services or to prohibit a  
18 plan or issuer from including providers only to the extent necessary to  
19 meet the needs of the plan's or issuer's participants, beneficiaries, or  
20 enrollees or from establishing any measure designed to maintain quality  
21 and control costs consistent with the responsibilities of the plan or  
22 issuer;

23 “(2) to override any State licensure or scope-of-practice law;

24 “(3) as requiring a plan or issuer that offers network coverage to  
25 include for participation every willing provider who meets the terms  
26 and conditions of the plan or issuer; or

27 “(4) as prohibiting a family practice physician with appropriate  
28 expertise from providing pediatric or obstetrical or gynecological care.

29 **“SEC. 2833. PROHIBITION AGAINST IMPROPER INCENTIVE ARRANGE-**  
30 **MENTS.**

31 “(a) IN GENERAL.—A group health plan and a health insurance issuer  
32 offering health insurance coverage may not operate any physician incentive  
33 plan (as defined in subparagraph (B) of section 1876(i)(8) of the Social Se-  
34 curity Act) unless the requirements described in clauses (i), (ii)(I), and (iii)  
35 of subparagraph (A) of such section are met with respect to such a plan.

36 “(b) APPLICATION.—For purposes of carrying out paragraph (1), any  
37 reference in section 1876(i)(8) of the Social Security Act to the Secretary,  
38 an eligible organization, or an individual enrolled with the organization shall  
39 be treated as a reference to the applicable authority, a group health plan  
40 or health insurance issuer, respectively, and a participant, beneficiary, or  
41 enrollee with the plan or organization, respectively.

1 “(c) CONSTRUCTION.—Nothing in this section shall be construed as  
2 prohibiting all capitation and similar arrangements or all provider discount  
3 arrangements.

4 **“SEC. 2834. PAYMENT OF CLEAN CLAIMS.**

5 “A group health plan, and a health insurance issuer offering group  
6 health insurance coverage, shall provide for prompt payment of claims sub-  
7 mitted for health care services or supplies furnished to a participant, bene-  
8 ficiary, or enrollee with respect to benefits covered by the plan or issuer, in  
9 a manner consistent with the provisions of sections 1816(c)(2) and  
10 1842(c)(2) of the Social Security Act (42 U.S.C. 1395h(c)(2) and 42 U.S.C.  
11 1395u(c)(2)), except that for purposes of this section, subparagraph (C) of  
12 section 1816(c)(2) of the Social Security Act shall be treated as applying  
13 to claims received from a participant, beneficiary, or enrollee as well as  
14 claims referred to in such subparagraph.

15 **“Subtitle E—Definitions**

16 **“SEC. 2841. DEFINITIONS.**

17 “(a) INCORPORATION OF GENERAL DEFINITIONS.—Except as other-  
18 wise provided, the provisions of section 2791 shall apply for purposes of this  
19 title in the same manner as they apply for purposes of title XXVII.

20 “(b) ADDITIONAL DEFINITIONS.—For purposes of this title:

21 “(1) APPLICABLE AUTHORITY.—The term ‘applicable authority’  
22 means—

23 “(A) in the case of a group health plan, the Secretary of  
24 Health and Human Services; and

25 “(B) in the case of a health insurance issuer with respect to  
26 a specific provision of this title, the applicable State authority (as  
27 defined in section 2791(d) of the Public Health Service Act), or  
28 the Secretary of Health and Human Services, if such Secretary is  
29 enforcing such provision under section 2722(a)(2) or 2761(a)(2)  
30 of the Public Health Service Act.

31 “(2) CLINICAL PEER.—The term ‘clinical peer’ means, with re-  
32 spect to a review or appeal, a practicing physician or other health care  
33 professional who holds a nonrestricted license and who is—

34 “(A) appropriately certified by a nationally recognized, peer  
35 reviewed accrediting body in the same or similar specialty as typi-  
36 cally manages the medical condition, procedure, or treatment  
37 under review or appeal, or

38 “(B) is trained and experienced in managing such condition,  
39 procedure, or treatment,



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1 and includes a pediatric specialist where appropriate; except that only  
2 a physician may be a clinical peer with respect to the review or appeal  
3 of treatment recommended or rendered by a physician.

4 “(3) ENROLLEE.—The term ‘enrollee’ means, with respect to  
5 health insurance coverage offered by a health insurance issuer, an indi-  
6 vidual enrolled with the issuer to receive such coverage.

7 “(4) HEALTH CARE PROFESSIONAL.—The term ‘health care pro-  
8 fessional’ means an individual who is licensed, accredited, or certified  
9 under State law to provide specified health care services and who is op-  
10 erating within the scope of such licensure, accreditation, or certifi-  
11 cation.

12 “(5) HEALTH CARE PROVIDER.—The term ‘health care provider’  
13 includes a physician or other health care professional, as well as an in-  
14 stitutional or other facility or agency that provides health care services  
15 and that is licensed, accredited, or certified to provide health care items  
16 and services under applicable State law.

17 “(6) NETWORK.—The term ‘network’ means, with respect to a  
18 group health plan or health insurance issuer offering health insurance  
19 coverage, the participating health care professionals and providers  
20 through whom the plan or issuer provides health care items and serv-  
21 ices to participants, beneficiaries, or enrollees.

22 “(7) NONPARTICIPATING.—The term ‘nonparticipating’ means,  
23 with respect to a health care provider that provides health care items  
24 and services to a participant, beneficiary, or enrollee under group  
25 health plan or health insurance coverage, a health care provider that  
26 is not a participating health care provider with respect to such items  
27 and services.

28 “(8) PARTICIPATING.—The term ‘participating’ means, with re-  
29 spect to a health care provider that provides health care items and  
30 services to a participant, beneficiary, or enrollee under group health  
31 plan or health insurance coverage offered by a health insurance issuer,  
32 a health care provider that furnishes such items and services under a  
33 contract or other arrangement with the plan or issuer.

34 “(9) PHYSICIAN.—The term ‘physician’ means an allopathic or os-  
35 teopathic physician.

36 “(10) PRACTICING PHYSICIAN.—The term ‘practicing physician’  
37 means a physician who is licensed in the State in which the physician  
38 furnishes professional services and who provides professional services to  
39 individual patients on average at least two full days per week.

40 “(11) PRIOR AUTHORIZATION.—The term ‘prior authorization’  
41 means the process of obtaining prior approval from a health insurance

1 issuer or group health plan for the provision or coverage of medical  
2 services.

3 **“SEC. 2842. RULE OF CONSTRUCTION.**

4 “(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO  
5 HEALTH INSURANCE ISSUERS.—

6 “(1) IN GENERAL.—Subject to paragraph (2), this title shall not  
7 be construed to supersede any provision of State law which establishes,  
8 implements, or continues in effect any standard or requirement solely  
9 relating to health insurance issuers except to the extent that such  
10 standard or requirement prevents the application of a requirement of  
11 this title.

12 “(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH  
13 PLANS.—Nothing in this title shall be construed to affect or modify the  
14 provisions of section 514 of the Employee Retirement Income Security  
15 Act of 1974.

16 “(b) DEFINITIONS.—For purposes of this section:

17 “(1) STATE LAW.—The term ‘State law’ includes all laws, deci-  
18 sions, rules, regulations, or other State action having the effect of law,  
19 of any State. A law of the United States applicable only to the District  
20 of Columbia shall be treated as a State law rather than a law of the  
21 United States.

22 “(2) STATE.—The term ‘State’ includes a State, the District of  
23 Columbia, the Northern Mariana Islands, any political subdivisions of  
24 a State or such Islands, or any agency or instrumentality of either.

25 **“SEC. 2843. EXCLUSIONS.**

26 “(a) NO BENEFIT REQUIREMENTS.—Nothing in this title shall be con-  
27 strued to require a group health plan or a health insurance issuer offering  
28 health insurance coverage to provide specific benefits under the terms of  
29 such plan or coverage, other than those provided under the terms of such  
30 plan or coverage.

31 “(b) EXCLUSION FOR FEE-FOR-SERVICE COVERAGE.—

32 “(1) IN GENERAL.—

33 “(A) GROUP HEALTH PLANS.—The provisions of sections  
34 2811 through 2821 shall not apply to a group health plan if the  
35 only coverage offered under the plan is fee-for-service coverage (as  
36 defined in paragraph (2)).

37 “(B) HEALTH INSURANCE COVERAGE.—The provisions of sec-  
38 tions 2801 through 2821 shall not apply to health insurance cov-  
39 erage if the only coverage offered under the coverage is fee-for-  
40 service coverage (as defined in paragraph (2)).

1           “(2) FEE-FOR-SERVICE COVERAGE DEFINED.—For purposes of  
2           this subsection, the term ‘fee-for-service coverage’ means coverage  
3           under a group health plan or health insurance coverage that—

4           “(A) reimburses hospitals, health professionals, and other  
5           providers on a fee-for-service basis without placing the provider at  
6           financial risk;

7           “(B) does not vary reimbursement for such a provider based  
8           on an agreement to contract terms and conditions or the utiliza-  
9           tion of health care items or services relating to such provider;

10          “(C) allows access to any provider that is lawfully authorized  
11          to provide the covered services and agree to accept the terms and  
12          conditions of payment established under the plan or by the issuer;  
13          and

14          “(D) for which the plan or issuer does not require prior au-  
15          thorization before providing for any health care services.

16       **“SEC. 2844. COVERAGE OF LIMITED SCOPE PLANS.**

17          “Only for purposes of applying the requirements of this title under sec-  
18          tions 2707 and 2753, section 2791(c)(2)(A) shall be deemed not to apply.

19       **“SEC. 2845. REGULATIONS.**

20          “‘The Secretary of Health and Human Services shall issue such regula-  
21          tions as may be necessary or appropriate to carry out this title under sec-  
22          tions 2707 and 2753. The Secretary may promulgate such regulations in  
23          the form of interim final rules as may be necessary to carry out this title  
24          in a timely manner.

25       **“SEC. 2846. LIMITATION ON APPLICATION OF PROVISIONS RELATING**  
26       **TO GROUP HEALTH PLANS.**

27          “‘The requirements of this title shall apply with respect to group health  
28          plans only—

29               “(1) in the case of a plan that is a non-Federal governmental plan  
30               (as defined in section 2791(d)(8)(C)), and

31               “(2) with respect to health insurance coverage offered in connec-  
32               tion with a group health plan (including such a plan that is a church  
33               plan or a governmental plan), except that subtitle A shall apply with  
34               respect to such coverage only to the extent it is offered in connection  
35               with a non-Federal governmental plan or a church plan.”.

**TITLE II—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974**

**SEC. 201. APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.**

(a) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new section:

**“SEC. 714. PATIENT PROTECTION STANDARDS.**

“A group health plan (and a health insurance issuer offering group health insurance coverage in connection with such a plan) shall comply with the requirements of part 8 and such requirements shall be deemed to be incorporated into this section.”.

(b) SATISFACTION OF ERISA CLAIMS PROCEDURE REQUIREMENT.—Section 503 of such Act (29 U.S.C. 1133) is amended by inserting “(a)” after “SEC. 503.” and by adding at the end the following new subsection:

“(b) In the case of a group health plan (as defined in section 733) compliance with the requirements of subpart A of part 8 in the case of a claims denial shall be deemed compliance with subsection (a) with respect to such claims denial. For purposes of applying the previous sentence, the exceptions provided under section 732 shall be deemed to apply.”.

(c) CONFORMING AMENDMENTS.—(1) Section 732(a) of such Act (29 U.S.C. 1185(a)) is amended by striking “section 711” and inserting “sections 711 and 714”.

(2) The table of contents in section 1 of such Act is amended by inserting after the item relating to section 713 the following new item:

“Sec. 714. Patient protection standards.”.

**SEC. 202. IMPROVING MANAGED CARE.**

(a) IN GENERAL.—Subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new part:

“PART 8—IMPROVING MANAGED CARE

“SUBPART A—GRIEVANCE AND APPEALS

**“SEC. 801. UTILIZATION REVIEW ACTIVITIES.**

“(a) COMPLIANCE WITH REQUIREMENTS.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer that provides health insurance coverage in connection with such a plan, shall conduct utilization review activities in connection with the provision of benefits under such plan or coverage only in accordance

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1 with a utilization review program that meets the requirements of this  
2 section.

3 “(2) USE OF OUTSIDE AGENTS.—Nothing in this section shall be  
4 construed as preventing a group health plan or health insurance issuer  
5 from arranging through a contract or otherwise for persons or entities  
6 to conduct utilization review activities on behalf of the plan or issuer,  
7 so long as such activities are conducted in accordance with a utilization  
8 review program that meets the requirements of this section.

9 “(3) UTILIZATION REVIEW DEFINED.—For purposes of this sec-  
10 tion, the terms ‘utilization review’ and ‘utilization review activities’  
11 mean procedures used to monitor or evaluate the use or coverage, clin-  
12 ical necessity, appropriateness, efficacy, or efficiency of health care  
13 services, procedures or settings, and includes prospective review, con-  
14 current review, second opinions, case management, discharge planning,  
15 or retrospective review.

16 “(b) WRITTEN POLICIES AND CRITERIA.—

17 “(1) WRITTEN POLICIES.—A utilization review program shall be  
18 conducted consistent with written policies and procedures that govern  
19 all aspects of the program.

20 “(2) USE OF WRITTEN CRITERIA.—

21 “(A) IN GENERAL.—Such a program shall utilize written clin-  
22 ical review criteria developed with input from a range of appro-  
23 priate practicing physicians, as determined by the plan, pursuant  
24 to the program. Such criteria shall include written clinical review  
25 criteria that are based on valid clinical evidence where available  
26 and that are directed specifically at meeting the needs of at-risk  
27 populations and covered individuals with chronic conditions or se-  
28 vere illnesses, including gender-specific criteria and pediatric-spe-  
29 cific criteria where available and appropriate.

30 “(B) CONTINUING USE OF STANDARDS IN RETROSPECTIVE  
31 REVIEW.—If a health care service has been specifically pre-author-  
32 ized or approved for a participant or beneficiary under such a pro-  
33 gram, the program shall not, pursuant to retrospective review, re-  
34 vise or modify the specific standards, criteria, or procedures used  
35 for the utilization review for procedures, treatment, and services  
36 delivered to the individual during the same course of treatment.

37 “(C) REVIEW OF SAMPLE OF CLAIMS DENIALS.—Such a pro-  
38 gram shall provide for periodic evaluation at reasonable intervals  
39 of the clinical appropriateness of a sample of denials of claims for  
40 benefits.

41 “(c) CONDUCT OF PROGRAM ACTIVITIES.—

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1           “(1) ADMINISTRATION BY HEALTH CARE PROFESSIONALS.—A uti-  
2           lization review program shall be administered by appropriate physician  
3           specialists who shall be selected by the plan or issuer and who shall  
4           oversee review decisions.

5           “(2) USE OF QUALIFIED, INDEPENDENT PERSONNEL.—

6           “(A) IN GENERAL.—A utilization review program shall pro-  
7           vide for the conduct of utilization review activities only through  
8           personnel who are qualified and have received appropriate training  
9           in the conduct of such activities under the program.

10          “(B) PROHIBITION OF CONTINGENT COMPENSATION AR-  
11          RANGEMENTS.—Such a program shall not, with respect to utiliza-  
12          tion review activities, permit or provide compensation or anything  
13          of value to its employees, agents, or contractors in a manner that  
14          encourages denials of claims for benefits. This subparagraph shall  
15          not preclude any capitation arrangements between plans and pro-  
16          viders.

17          “(C) PROHIBITION OF CONFLICTS.—Such a program shall  
18          not permit a health care professional who is providing health care  
19          services to an individual to perform utilization review activities in  
20          connection with the health care services being provided to the indi-  
21          vidual.

22          “(3) ACCESSIBILITY OF REVIEW.—Such a program shall provide  
23          that appropriate personnel performing utilization review activities  
24          under the program, including the utilization review administrator, are  
25          reasonably accessible by toll-free telephone during normal business  
26          hours to discuss patient care and allow response to telephone requests,  
27          and that appropriate provision is made to receive and respond promptly  
28          to calls received during other hours.

29          “(4) LIMITS ON FREQUENCY.—Such a program shall not provide  
30          for the performance of utilization review activities with respect to a  
31          class of services furnished to an individual more frequently than is rea-  
32          sonably required to assess whether the services under review are medi-  
33          cally necessary or appropriate.

34          “(d) DEADLINE FOR DETERMINATIONS.—

35          “(1) PRIOR AUTHORIZATION SERVICES.—

36          “(A) IN GENERAL.—Except as provided in paragraph (2), in  
37          the case of a utilization review activity involving the prior author-  
38          ization of health care items and services for an individual, the uti-  
39          lization review program shall make a determination concerning  
40          such authorization, and provide notice of the determination to the  
41          individual or the individual’s designee and the individual’s health

1 care provider by telephone and in printed or electronic form, no  
2 later than the deadline specified in subparagraph (B). The pro-  
3 vider involved shall provide timely access to information relevant  
4 to the matter of the review decision.

5 “(B) DEADLINE.—

6 “(i) IN GENERAL.—Subject to clauses (ii) and (iii), the  
7 deadline specified in this subparagraph is 14 days after the  
8 earliest date as of which the request for prior authorization  
9 has been received and all necessary information has been pro-  
10 vided.

11 “(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDI-  
12 TIONAL INFORMATION REQUIRED.—If a utilization review  
13 program—

14 “(I) receives a request for a prior authorization,

15 “(II) determines that additional information is nec-  
16 essary to complete the review and make the determina-  
17 tion on the request,

18 “(III) notifies the requester, not later than 5 busi-  
19 ness days after the date of receiving the request, of the  
20 need for such specified additional information, and

21 “(IV) requires the requester to submit specified in-  
22 formation not later than 2 business days after notifica-  
23 tion,

24 the deadline specified in this subparagraph is 14 days after  
25 the date the program receives the specified additional infor-  
26 mation, but in no case later than 28 days after the date of  
27 receipt of the request for the prior authorization. This clause  
28 shall not apply if the deadline is specified in clause (iii).

29 “(iii) EXPEDITED CASES.—In the case of a situation de-  
30 scribed in section 802(c)(1)(A), the deadline specified in this  
31 subparagraph is 48 hours after the time of the request for  
32 prior authorization.

33 “(2) ONGOING CARE.—

34 “(A) CONCURRENT REVIEW.—

35 “(i) IN GENERAL.—Subject to subparagraph (B), in the  
36 case of a concurrent review of ongoing care (including hos-  
37 pitalization), which results in a termination or reduction of  
38 such care, the plan must provide by telephone and in printed  
39 or electronic form notice of the concurrent review determina-  
40 tion to the individual or the individual’s designee and the in-  
41 dividual’s health care provider as soon as possible in accord-

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1           ance with the medical exigencies of the case, with sufficient  
2           time prior to the termination or reduction to allow for an ap-  
3           peal under section 802(c)(1)(A) to be completed before the  
4           termination or reduction takes effect.

5           “(ii) CONTENTS OF NOTICE.—Such notice shall include,  
6           with respect to ongoing health care items and services, the  
7           number of ongoing services approved, the new total of ap-  
8           proved services, the date of onset of services, and the next re-  
9           view date, if any, as well as a statement of the individual’s  
10          rights to further appeal.

11          “(B) EXCEPTION.—Subparagraph (A) shall not be inter-  
12          preted as requiring plans or issuers to provide coverage of care  
13          that would exceed the coverage limitations for such care.

14          “(3) PREVIOUSLY PROVIDED SERVICES.—In the case of a utiliza-  
15          tion review activity involving retrospective review of health care services  
16          previously provided for an individual, the utilization review program  
17          shall make a determination concerning such services, and provide notice  
18          of the determination to the individual or the individual’s designee and  
19          the individual’s health care provider by telephone and in printed or  
20          electronic form, within 30 days of the date of receipt of information  
21          that is reasonably necessary to make such determination, but in no  
22          case later than 60 days after the date of receipt of the claim for bene-  
23          fits.

24          “(4) FAILURE TO MEET DEADLINE.—In a case in which a group  
25          health plan or health insurance issuer fails to make a determination  
26          on a claim for benefit under paragraph (1), (2)(A), or (3) by the appli-  
27          cable deadline established under the respective paragraph, the failure  
28          shall be treated under this subpart as a denial of the claim as of the  
29          date of the deadline.

30          “(5) REFERENCE TO SPECIAL RULES FOR EMERGENCY SERVICES,  
31          MAINTENANCE CARE, POST-STABILIZATION CARE, AND EMERGENCY AM-  
32          BULANCE SERVICES.—For waiver of prior authorization requirements  
33          in certain cases involving emergency services, maintenance care and  
34          post-stabilization care, and emergency ambulance services, see sub-  
35          sections (a)(1), (b), and (c)(1) of section 813, respectively.

36          “(e) NOTICE OF DENIALS OF CLAIMS FOR BENEFITS.—

37          “(1) IN GENERAL.—Notice of a denial of claims for benefits under  
38          a utilization review program shall be provided in printed or electronic  
39          form and written in a manner calculated to be understood by the par-  
40          ticipant or beneficiary and shall include—



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1 “(A) the reasons for the denial (including the clinical ration-  
2 ale);

3 “(B) instructions on how to initiate an appeal under section  
4 802; and

5 “(C) notice of the availability, upon request of the individual  
6 (or the individual’s designee) of the clinical review criteria relied  
7 upon to make such denial.

8 “(2) SPECIFICATION OF ANY ADDITIONAL INFORMATION.—Such a  
9 notice shall also specify what (if any) additional necessary information  
10 must be provided to, or obtained by, the person making the denial in  
11 order to make a decision on such an appeal.

12 “(f) CLAIM FOR BENEFITS AND DENIAL OF CLAIM FOR BENEFITS DE-  
13 FINED.—For purposes of this subpart:

14 “(1) CLAIM FOR BENEFITS.—The term ‘claim for benefits’ means  
15 any request for coverage (including authorization of coverage), or for  
16 payment in whole or in part, for an item or service under a group  
17 health plan or health insurance coverage offered in connection with  
18 such a plan.

19 “(2) DENIAL OF CLAIM FOR BENEFITS.—The term ‘denial’ means,  
20 with respect to a claim for benefits, a denial, or a failure to act on  
21 a timely basis upon, in whole or in part, the claim for benefits and in-  
22 cludes a failure to provide or pay for benefits (including items and serv-  
23 ices) required to be provided or paid for under this part.

24 **“SEC. 802. INTERNAL APPEALS PROCEDURES.**

25 “(a) RIGHT OF REVIEW.—

26 “(1) IN GENERAL.—Each group health plan, and each health in-  
27 surance issuer offering health insurance coverage in connection with  
28 such a plan—

29 “(A) shall provide adequate notice in written or electronic  
30 form to any participant or beneficiary under such plan whose  
31 claim for benefits under the plan or coverage has been denied  
32 (within the meaning of section 801(f)(2)), setting forth the specific  
33 reasons for such denial of claim for benefits and rights to any fur-  
34 ther review or appeal, written in layman’s terms to be understood  
35 by the participant or beneficiary; and

36 “(B) shall afford such a participant or beneficiary (and any  
37 provider or other person acting on behalf of such an individual  
38 with the individual’s consent or without such consent if the indi-  
39 vidual is medically unable to provide such consent) who is dissatis-  
40 fied with such a denial of claim for benefits a reasonable oppor-  
41 tunity of not less than 180 days to request and obtain a full and

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1 fair review by a named fiduciary (with respect to such plan) or  
2 named appropriate individual (with respect to such coverage) of  
3 the decision denying the claim.

4 “(2) TREATMENT OF ORAL REQUESTS.—The request for review  
5 under paragraph (1)(B) may be made orally, but, in the case of an oral  
6 request, shall be followed by a request in written or electronic form.

7 “(b) INTERNAL REVIEW PROCESS.—

8 “(1) CONDUCT OF REVIEW.—

9 “(A) IN GENERAL.—A review of a denial of claim under this  
10 section shall be made by an individual (who shall be a physician  
11 in a case involving medical judgment) who has been selected by  
12 the plan or issuer and who did not make the initial denial in the  
13 internally appealable decision, except that in the case of limited  
14 scope coverage (as defined in subparagraph (B)) an appropriate  
15 specialist shall review the decision.

16 “(B) LIMITED SCOPE COVERAGE DEFINED.—For purposes of  
17 subparagraph (A), the term ‘limited scope coverage’ means a  
18 group health plan or health insurance coverage the only benefits  
19 under which are for benefits described in section 2791(c)(2)(A) of  
20 the Public Health Service Act (42 U.S.C. 300gg–91(c)(2)).

21 “(2) TIME LIMITS FOR INTERNAL REVIEWS.—

22 “(A) IN GENERAL.—Having received such a request for re-  
23 view of a denial of claim, the plan or issuer shall, in accordance  
24 with the medical exigencies of the case but not later than the  
25 deadline specified in subparagraph (B), complete the review on the  
26 denial and transmit to the participant, beneficiary, or other person  
27 involved a decision that affirms, reverses, or modifies the denial.  
28 If the decision does not reverse the denial, the plan or issuer shall  
29 transmit, in printed or electronic form, a notice that sets forth the  
30 grounds for such decision and that includes a description of rights  
31 to any further appeal. Such decision shall be treated as the final  
32 decision of the plan. Failure to issue such a decision by such dead-  
33 line shall be treated as a final decision affirming the denial of  
34 claim.

35 “(B) DEADLINE.—

36 “(i) IN GENERAL.—Subject to clauses (ii) and (iii), the  
37 deadline specified in this subparagraph is 14 days after the  
38 earliest date as of which the request for prior authorization  
39 has been received and all necessary information has been pro-  
40 vided. The provider involved shall provide timely access to in-  
41 formation relevant to the matter of the review decision.

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1                   “(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDI-  
2                   TIONAL INFORMATION REQUIRED.—If a group health plan or  
3                   health insurance issuer—

4                   “(I) receives a request for internal review,

5                   “(II) determines that additional information is nec-  
6                   essary to complete the review and make the determina-  
7                   tion on the request,

8                   “(III) notifies the requester, not later than 5 busi-  
9                   ness days after the date of receiving the request, of the  
10                  need for such specified additional information, and

11                  “(IV) requires the requester to submit specified in-  
12                  formation not later than 48 hours after notification,  
13                  the deadline specified in this subparagraph is 14 days after  
14                  the date the plan or issuer receives the specified additional in-  
15                  formation, but in no case later than 28 days after the date  
16                  of receipt of the request for the internal review. This clause  
17                  shall not apply if the deadline is specified in clause (iii).

18                  “(iii) EXPEDITED CASES.—In the case of a situation de-  
19                  scribed in subsection (c)(1)(A), the deadline specified in this  
20                  subparagraph is 48 hours after the time of request for review.

21                  “(c) EXPEDITED REVIEW PROCESS.—

22                  “(1) IN GENERAL.—A group health plan, and a health insurance  
23                  issuer, shall establish procedures in writing for the expedited consider-  
24                  ation of requests for review under subsection (b) in situations—

25                  “(A) in which, as determined by the plan or issuer or as cer-  
26                  tified in writing by a treating physician, the application of the nor-  
27                  mal timeframe for making the determination could seriously jeop-  
28                  ardize the life or health of the participant or beneficiary or such  
29                  individual’s ability to regain maximum function; or

30                  “(B) described in section 801(d)(2) (relating to requests for  
31                  continuation of ongoing care which would otherwise be reduced or  
32                  terminated).

33                  “(2) PROCESS.—Under such procedures—

34                  “(A) the request for expedited review may be submitted orally  
35                  or in writing by an individual or provider who is otherwise entitled  
36                  to request the review;

37                  “(B) all necessary information, including the plan’s or  
38                  issuer’s decision, shall be transmitted between the plan or issuer  
39                  and the requester by telephone, facsimile, or other similarly expe-  
40                  ditious available method; and

1 “(C) the plan or issuer shall expedite the review in the case  
2 of any of the situations described in subparagraph (A) or (B) of  
3 paragraph (1).

4 “(3) DEADLINE FOR DECISION.—The decision on the expedited re-  
5 view must be made and communicated to the parties as soon as pos-  
6 sible in accordance with the medical exigencies of the case, and in no  
7 event later than 48 hours after the time of receipt of the request for  
8 expedited review, except that in a case described in paragraph (1)(B),  
9 the decision must be made before the end of the approved period of  
10 care.

11 “(d) WAIVER OF PROCESS.—A plan or issuer may waive its rights for  
12 an internal review under subsection (b). In such case the participant or ben-  
13 efiary involved (and any designee or provider involved) shall be relieved of  
14 any obligation to complete the review involved and may, at the option of  
15 such participant, beneficiary, designee, or provider, proceed directly to seek  
16 further appeal through any applicable external appeals process.

17 **“SEC. 803. EXTERNAL APPEALS PROCEDURES.**

18 “(a) RIGHT TO EXTERNAL APPEAL.—

19 “(1) IN GENERAL.—A group health plan, and a health insurance  
20 issuer offering health insurance coverage in connection with such a  
21 plan, shall provide for an external appeals process that meets the re-  
22 quirements of this section in the case of an externally appealable deci-  
23 sion described in paragraph (2), for which a timely appeal is made  
24 (within a reasonable period not to exceed 365 days) either by the plan  
25 or issuer or by the participant or beneficiary (and any provider or other  
26 person acting on behalf of such an individual with the individual’s con-  
27 sent or without such consent if such an individual is medically unable  
28 to provide such consent).

29 “(2) EXTERNALLY APPEALABLE DECISION DEFINED.—

30 “(A) IN GENERAL.—For purposes of this section, the term  
31 ‘externally appealable decision’ means a denial of claim for bene-  
32 fits (as defined in section 801(f)(2)), if—

33 “(i) the item or service involved is covered under the  
34 plan or coverage,

35 “(ii) the amount involved exceeds \$100, increased or de-  
36 creased, for each calendar year that ends after December 31,  
37 2001, by the same percentage as the percentage by which the  
38 medical care expenditure category of the Consumer Price  
39 Index for All Urban Consumers (United States city average),  
40 published by the Bureau of Labor Statistics, for September

1 of the preceding calendar year has increased or decreased  
2 from such index for September 2000, and

3 “(iii) the requirements of subparagraph (B) are met with  
4 respect to such denial.

5 Such term also includes a failure to meet an applicable deadline  
6 for internal review under section 802 or such standards as are es-  
7 tablished pursuant to section 818.

8 “(B) REQUIREMENTS.—For purposes of subparagraph  
9 (A)(iii), the requirements of this subparagraph are met with re-  
10 spect to a denial of a claim for benefits if—

11 “(i) the denial is based in whole or in part on a decision  
12 that the item or service is not medically necessary or appro-  
13 priate or is investigational or experimental, or

14 “(ii) in such denial, the decision as to whether an item  
15 or service is covered involves a medical judgment.

16 “(C) EXCLUSIONS.—The term ‘externally appealable decision’  
17 does not include—

18 “(i) specific exclusions or express limitations on the  
19 amount, duration, or scope of coverage; or

20 “(ii) a decision regarding eligibility for any benefits.

21 “(3) EXHAUSTION OF INTERNAL REVIEW PROCESS.—Except as  
22 provided under section 802(d), a plan or issuer may condition the use  
23 of an external appeal process in the case of an externally appealable  
24 decision upon a final decision in an internal review under section 802,  
25 but only if the decision is made in a timely basis consistent with the  
26 deadlines provided under this subpart.

27 “(4) FILING FEE REQUIREMENT.—

28 “(A) IN GENERAL.—A plan or issuer may condition the use  
29 of an external appeal process upon payment in advance to the plan  
30 or issuer of a \$25 filing fee.

31 “(B) REFUNDING FEE IN CASE OF SUCCESSFUL APPEALS.—  
32 The plan or issuer shall refund payment of the filing fee under  
33 this paragraph if the recommendation of the external appeal entity  
34 is to reverse the denial of a claim for benefits which is the subject  
35 of the appeal.

36 “(b) GENERAL ELEMENTS OF EXTERNAL APPEALS PROCESS.—

37 “(1) USE OF QUALIFIED EXTERNAL APPEAL ENTITY.—

38 “(A) IN GENERAL.—The external appeal process under this  
39 section of a plan or issuer shall be conducted between the plan or  
40 issuer and one or more qualified external appeal entities (as de-  
41 fined in subsection (c)). Nothing in this subsection shall be con-

1           strued as requiring that such procedures provide for the selection  
2           for any plan of more than one such entity.

3           “(B) LIMITATION ON PLAN OR ISSUER SELECTION.—The Sec-  
4           retary shall implement procedures to assure that the selection  
5           process among qualified external appeal entities will not create any  
6           incentives for external appeal entities to make a decision in a bi-  
7           ased manner.

8           “(C) OTHER TERMS AND CONDITIONS.—The terms and con-  
9           ditions of this paragraph shall be consistent with the standards  
10          the Secretary shall establish to assure there is no real or apparent  
11          conflict of interest in the conduct of external appeal activities. All  
12          costs of the process (except those incurred by the participant, ben-  
13          eficiary, or treating professional in support of the appeal) shall be  
14          paid by the plan or issuer, and not by the participant or bene-  
15          ficiary. The previous sentence shall not be construed as applying  
16          to the imposition of a filing fee under subsection (a)(4).

17          “(2) ELEMENTS OF PROCESS.—An external appeal process shall  
18          be conducted consistent with standards established by the Secretary  
19          that include at least the following:

20               “(A) FAIR AND DE NOVO DETERMINATION.—The process  
21               shall provide for a fair, de novo determination described in sub-  
22               paragraph (B) based on evidence described in subparagraphs (C)  
23               and (D).

24               “(B) STANDARD OF REVIEW.—An external appeal entity shall  
25               determine whether the plan’s or issuer’s decision is appropriate for  
26               the medical condition of the patient involved (as determined by the  
27               entity) taking into account as of the time of the entity’s deter-  
28               mination the patient’s medical condition and any relevant and reli-  
29               able evidence the entity obtains under subparagraphs (C) and (D).  
30               If the entity determines the decision is appropriate for such condi-  
31               tion, the entity shall affirm the decision and to the extent that the  
32               entity determines the decision is not appropriate for such condi-  
33               tion, the entity shall reverse the decision. Nothing in this subpara-  
34               graph shall be construed as providing for coverage of items or  
35               services not provided or covered by the plan or issuer.

36               “(C) REQUIRED CONSIDERATION OF CERTAIN MATTERS.—In  
37               making such determination, the external appeal entity shall con-  
38               sider, but not be bound by—

39                       “(i) any language in the plan or coverage document re-  
40                       lating to the definitions of the terms medical necessity, medi-

1 cally necessary or appropriate, or experimental, investiga-  
2 tional, or related terms;

3 “(ii) the decision made by the plan or issuer upon inter-  
4 nal review under section 802 and any guidelines or standards  
5 used by the plan or issuer in reaching such decision; and

6 “(iii) the opinion of the individual’s treating physician or  
7 health care professional.

8 The entity also shall consider any personal health and medical in-  
9 formation supplied with respect to the individual whose denial of  
10 claim for benefits has been appealed. The entity also shall consider  
11 the results of studies that meet professionally recognized stand-  
12 ards of validity and replicability or that have been published in  
13 peer-reviewed journals.

14 “(D) ADDITIONAL EVIDENCE.—Such entity may also take  
15 into consideration but not be limited to the following evidence (to  
16 the extent available):

17 “(i) The results of professional consensus conferences.

18 “(ii) Practice and treatment policies.

19 “(iii) Community standard of care.

20 “(iv) Generally accepted principles of professional med-  
21 ical practice consistent with the best practice of medicine.

22 “(v) To the extent that the entity determines it to be  
23 free of any conflict of interest, the opinions of individuals who  
24 are qualified as experts in one or more fields of health care  
25 which are directly related to the matters under appeal.

26 “(vi) To the extent that the entity determines it to be  
27 free of any conflict of interest, the results of peer reviews con-  
28 ducted by the plan or issuer involved.

29 “(E) DETERMINATION CONCERNING EXTERNALLY APPEAL-  
30 ABLE DECISIONS.—

31 “(i) IN GENERAL.—A qualified external appeal entity  
32 shall determine—

33 “(I) whether a denial of claim for benefits is an ex-  
34 ternally appealable decision (within the meaning of sub-  
35 section (a)(2));

36 “(II) whether an externally appealable decision in-  
37 volves an expedited appeal;

38 “(III) for purposes of initiating an external review,  
39 whether the internal review process has been completed;  
40 and

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1 “(IV) whether the item or services is covered under  
2 the plan or coverage.

3 “(ii) CONSTRUCTION.—Nothing in a determination by a  
4 qualified external appeal entity under this section shall be  
5 construed as authorizing, or providing for, coverage of items  
6 and services for which benefits are not provided under the  
7 plan or coverage.

8 “(F) OPPORTUNITY TO SUBMIT EVIDENCE.—Each party to  
9 an externally appealable decision may submit evidence related to  
10 the issues in dispute.

11 “(G) PROVISION OF INFORMATION.—The plan or issuer in-  
12 volved shall provide to the external appeal entity timely access to  
13 information and to provisions of the plan or health insurance cov-  
14 erage relating to the matter of the externally appealable decision,  
15 as determined by the entity. The provider involved shall provide  
16 to the external appeal entity timely access to information relevant  
17 to the matter of the externally appealable decision, as determined  
18 by the entity.

19 “(H) TIMELY DECISIONS.—A determination by the external  
20 appeal entity on the decision shall—

21 “(i) be made orally or in written or electronic form and,  
22 if it is made orally, shall be supplied to the parties in written  
23 or electronic form as soon as possible;

24 “(ii) be made in accordance with the medical exigencies  
25 of the case involved, but in no event later than 21 days after  
26 the date (or, in the case of an expedited appeal, 48 hours  
27 after the time) of requesting an external appeal of the deci-  
28 sion;

29 “(iii) state, in layperson’s language, the scientific ration-  
30 ale for such determination as well as the basis for such deter-  
31 mination, including, if relevant, any basis in the terms or con-  
32 ditions of the plan or coverage; and

33 “(iv) inform the participant or beneficiary of the individ-  
34 ual’s rights (including any limitation on such rights) to seek  
35 binding arbitration or further review by the courts (or other  
36 process) of the external appeal determination.

37 “(I) COMPLIANCE WITH DETERMINATION.—If the external  
38 appeal entity determines that a denial of a claim for benefits was  
39 not reasonable and reverses the denial, the plan or issuer—

40 “(i) shall (upon the receipt of the determination) author-  
41 ize benefits in accordance with such determination;



1 “(ii) shall take such actions as may be necessary to pro-  
2 vide benefits (including items or services) in a timely manner  
3 consistent with such determination; and

4 “(iii) shall submit information to the entity documenting  
5 compliance with the entity’s determination and this subpara-  
6 graph.

7 “(J) CONSTRUCTION.—Nothing in this paragraph shall be  
8 construed as providing for coverage of items and services for which  
9 benefits are not provided under the plan or coverage.

10 “(c) QUALIFICATIONS OF EXTERNAL APPEAL ENTITIES.—

11 “(1) IN GENERAL.—For purposes of this section, the term ‘quali-  
12 fied external appeal entity’ means, in relation to a plan or issuer, an  
13 entity that is certified under paragraph (2) as meeting the following  
14 requirements:

15 “(A) The entity meets the independence requirements of  
16 paragraph (3).

17 “(B) The entity conducts external appeal activities through at  
18 least three clinical peers who are practicing physicians.

19 “(C) The entity has sufficient medical, legal, and other exper-  
20 tise and sufficient staffing to conduct external appeal activities for  
21 the plan or issuer on a timely basis consistent with subsection  
22 (b)(2)(G).

23 “(2) INITIAL CERTIFICATION OF EXTERNAL APPEAL ENTITIES.—

24 “(A) IN GENERAL.—In order to be treated as a qualified ex-  
25 ternal appeal entity with respect to a group health plan or a  
26 health insurance issuer in connection with a group health plan, the  
27 entity must be certified (and, in accordance with subparagraph  
28 (B), periodically recertified), under such standards as may be pre-  
29 scribed by the Secretary, as meeting the requirements of para-  
30 graph (1)—

31 “(i) by the Secretary;

32 “(ii) under a process recognized or approved by the Sec-  
33 retary; or

34 “(iii) to the extent provided in subparagraph (C)(i), by  
35 a qualified private standard-setting organization (certified  
36 under such subparagraph), if elected by the entity.

37 “(B) RECERTIFICATION PROCESS.—The Secretary shall de-  
38 velop standards for the recertification of external appeal entities.  
39 Such standards shall include a review of—

40 “(i) the number of cases reviewed;

41 “(ii) a summary of the disposition of those cases;

1 “(iii) the length of time in making determinations on  
2 those cases;

3 “(iv) updated information of what was required to be  
4 submitted as a condition of certification for the entity’s per-  
5 formance of external appeal activities; and

6 “(v) information necessary to assure that the entity  
7 meets the independence requirements (described in paragraph  
8 (3)) with respect to plans and issuers for which it conducts  
9 external review activities.

10 “(C) CERTIFICATION OF QUALIFIED PRIVATE STANDARD-SET-  
11 TING ORGANIZATIONS.—For purposes of subparagraph (A)(iii), the  
12 Secretary shall provide for a process for certification (and periodic  
13 recertification) of qualified private standard-setting organizations  
14 which provide for certification of external appeal entities. Such an  
15 organization shall only be certified if the organization does not  
16 certify an external appeal entity unless it meets standards at least  
17 as stringent as the standards required for certification of such an  
18 entity by the Secretary under subparagraph (A)(i).

19 “(D) CONSTRUCTION.—Nothing in subparagraph (A) shall be  
20 construed as permitting the Secretary to delegate certification or  
21 regulatory authority under clause (i) of such subparagraph to any  
22 person outside the Department of Labor.

23 “(3) INDEPENDENCE REQUIREMENTS.—

24 “(A) IN GENERAL.—A clinical peer or other entity meets the  
25 independence requirements of this paragraph if—

26 “(i) the peer or entity is not affiliated with any related  
27 party;

28 “(ii) any compensation received by such peer or entity in  
29 connection with the external review is reasonable and not con-  
30 tingent on any decision rendered by the peer or entity;

31 “(iii) the plan and the issuer (if any) have no recourse  
32 against the peer or entity in connection with the external re-  
33 view; and

34 “(iv) the peer or entity does not otherwise have a conflict  
35 of interest with a related party.

36 “(B) RELATED PARTY.—For purposes of this paragraph, the  
37 term ‘related party’ means—

38 “(i) a group health plan or health insurance coverage of-  
39 fered in connection with such a plan, the plan or the health  
40 insurance issuer offering such coverage, or any plan sponsor,

1 fiduciary, officer, director, or management employee of such  
2 plan or issuer;

3 “(ii) the health care professional that provided the health  
4 care involved in the coverage decision;

5 “(iii) the institution at which the health care involved in  
6 the coverage decision is provided; or

7 “(iv) the manufacturer of any drug or other item that  
8 was included in the health care involved in the coverage deci-  
9 sion.

10 “(C) AFFILIATED.—For purposes of this paragraph, the term  
11 ‘affiliated’ means, in connection with any peer or entity, having a  
12 familial, financial, or fiduciary relationship with such peer or enti-  
13 ty.

14 “(4) LIMITATION ON LIABILITY OF REVIEWERS.—No qualified ex-  
15 ternal appeal entity having a contract with a plan or issuer under this  
16 part and no person who is employed by any such entity or who fur-  
17 nishes professional services to such entity, shall be held by reason of  
18 the performance of any duty, function, or activity required or author-  
19 ized pursuant to this section, to have violated any criminal law, or to  
20 be civilly liable under any law of the United States or of any State (or  
21 political subdivision thereof) if due care was exercised in the perform-  
22 ance of such duty, function, or activity and there was no actual malice  
23 or gross misconduct in the performance of such duty, function, or ac-  
24 tivity.

25 “(d) EXTERNAL APPEAL DETERMINATION BINDING ON PLAN.—

26 “(1) IN GENERAL.—The determination by an external appeal enti-  
27 ty shall be binding on the plan (and issuer, if any) involved in the de-  
28 termination.

29 “(2) PROTECTION OF LEGAL RIGHTS.—Nothing in this subpart  
30 shall be construed as removing any legal rights of participants, bene-  
31 ficiaries, and others under State or Federal law, including the right to  
32 file judicial actions to enforce rights.

33 “(e) PENALTIES AGAINST AUTHORIZED OFFICIALS FOR REFUSING TO  
34 AUTHORIZE THE DETERMINATION OF AN EXTERNAL APPEAL ENTITY.—

35 “(1) MONETARY PENALTIES.—In any case in which the deter-  
36 mination of an external appeal entity is not followed in a timely fashion  
37 by a group health plan, or by a health insurance issuer offering health  
38 insurance coverage in connection with such a plan, any named fiduciary  
39 who, acting in the capacity of authorizing the benefit, causes such re-  
40 fusals may, in the discretion in a court of competent jurisdiction, be lia-  
41 ble to an aggrieved participant or beneficiary for a civil penalty in an

1 amount of up to \$1,000 a day from the date on which the determina-  
2 tion was transmitted to the plan or issuer by the external appeal entity  
3 until the date the refusal to provide the benefit is corrected.

4 “(2) CEASE AND DESIST ORDER AND ORDER OF ATTORNEY’S  
5 FEES.—In any action described in paragraph (1) brought by a partici-  
6 pant or beneficiary with respect to a group health plan, or a health in-  
7 surance issuer offering health insurance coverage in connection with  
8 such a plan, in which a plaintiff alleges that a person referred to in  
9 such paragraph has taken an action resulting in a refusal of a benefit  
10 determined by an external appeal entity in violation of such terms of  
11 the plan, coverage, or this subpart, or has failed to take an action for  
12 which such person is responsible under the plan, coverage, or this part  
13 and which is necessary under the plan or coverage for authorizing a  
14 benefit, the court shall cause to be served on the defendant an order  
15 requiring the defendant—

16 “(A) to cease and desist from the alleged action or failure to  
17 act; and

18 “(B) to pay to the plaintiff a reasonable attorney’s fee and  
19 other reasonable costs relating to the prosecution of the action on  
20 the charges on which the plaintiff prevails.

21 “(f) PROTECTION OF LEGAL RIGHTS.—Nothing in this subpart shall  
22 be construed as removing or limiting any legal rights of participants, bene-  
23 ficiaries, and others under State or Federal law (including section 502), in-  
24 cluding the right to file judicial actions to enforce rights.

25 **“SEC. 804. ESTABLISHMENT OF A GRIEVANCE PROCESS.**

26 “(a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

27 “(1) IN GENERAL.—A group health plan, and a health insurance  
28 issuer in connection with the provision of health insurance coverage in  
29 connection with such a plan, shall establish and maintain a system to  
30 provide for the presentation and resolution of oral and written griev-  
31 ances brought by individuals who are participants or beneficiaries or  
32 health care providers or other individuals acting on behalf of an indi-  
33 vidual and with the individual’s consent or without such consent if the  
34 individual is medically unable to provide such consent, regarding any  
35 aspect of the plan’s or issuer’s services.

36 “(2) GRIEVANCE DEFINED.—In this section, the term ‘grievance’  
37 means any question, complaint, or concern brought by a participant or  
38 beneficiary that is not a claim for benefits.

39 “(b) GRIEVANCE SYSTEM.—Such system shall include the following  
40 components with respect to individuals who are participants or beneficiaries:

1           “(1) Written notification to all such individuals and providers of  
2           the telephone numbers and business addresses of the plan or issuer  
3           personnel responsible for resolution of grievances and appeals.

4           “(2) A system to record and document, over a period of at least  
5           3 previous years beginning two months after the date of the enactment  
6           of this Act, all grievances and appeals made and their status.

7           “(3) A process providing processing and resolution of grievances  
8           within 60 days.

9           “(4) Procedures for follow-up action, including the methods to in-  
10          form the person making the grievance of the resolution of the griev-  
11          ance.

12        Grievances are not subject to appeal under the previous provisions of this  
13        subpart.

14                               “SUBPART B—ACCESS TO CARE

15        **“SEC. 812. CHOICE OF HEALTH CARE PROFESSIONAL.**

16           “(a) PRIMARY CARE.—If a group health plan, or a health insurance  
17           issuer that offers health insurance coverage in connection with such a plan,  
18           requires or provides for designation by a participant or beneficiary of a par-  
19           ticipating primary care provider, then the plan or issuer shall permit each  
20           participant and beneficiary to designate any participating primary care pro-  
21           vider who is available to accept such individual.

22           “(b) SPECIALISTS.—A group health plan and a health insurance issuer  
23           that offers health insurance coverage in connection with such a plan shall  
24           permit each participant or beneficiary to receive medically necessary or ap-  
25           propriate specialty care, pursuant to appropriate referral procedures, from  
26           any qualified participating health care professional who is available to ac-  
27           cept such individual for such care.

28        **“SEC. 813. ACCESS TO EMERGENCY CARE.**

29           “(a) COVERAGE OF EMERGENCY SERVICES.—

30           “(1) IN GENERAL.—If a group health plan, or health insurance  
31           coverage offered by a health insurance issuer in connection with such  
32           a plan, provides or covers any benefits with respect to services in an  
33           emergency department of a hospital, the plan or issuer shall cover  
34           emergency services (as defined in paragraph (2)(B))—

35                               “(A) without the need for any prior authorization determina-  
36                               tion;

37                               “(B) whether the health care provider furnishing such serv-  
38                               ices is a participating provider with respect to such services;

39                               “(C) in a manner so that, if such services are provided to a  
40                               participant or beneficiary—

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1 “(i) by a nonparticipating health care provider with or  
2 without prior authorization, or

3 “(ii) by a participating health care provider without prior  
4 authorization,

5 the participant or beneficiary is not liable for amounts that exceed  
6 the amounts of liability that would be incurred if the services were  
7 provided by a participating health care provider with prior author-  
8 ization; and

9 “(D) without regard to any other term or condition of such  
10 coverage (other than exclusion or coordination of benefits, or an  
11 affiliation or waiting period, permitted under section 2701 of the  
12 Public Health Service Act, section 701, or section 9801 of the In-  
13 ternal Revenue Code of 1986, and other than applicable cost-shar-  
14 ing).

15 “(2) DEFINITIONS.—In this section:

16 “(A) EMERGENCY MEDICAL CONDITION.—The term ‘emer-  
17 gency medical condition’ means—

18 “(i) a medical condition manifesting itself by acute  
19 symptoms of sufficient severity (including severe pain) such  
20 that a prudent layperson, who possesses an average knowl-  
21 edge of health and medicine, could reasonably expect the ab-  
22 sence of immediate medical attention to result in a condition  
23 described in clause (i), (ii), or (iii) of section 1867(e)(1)(A)  
24 of the Social Security Act; and

25 “(ii) a medical condition manifesting itself in a neonate  
26 by acute symptoms of sufficient severity (including severe  
27 pain) such that a prudent health care professional could rea-  
28 sonably expect the absence of immediate medical attention to  
29 result in a condition described in clause (i), (ii), or (iii) of sec-  
30 tion 1867(e)(1)(A) of the Social Security Act.

31 “(B) EMERGENCY SERVICES.—The term ‘emergency services’  
32 means—

33 “(i) with respect to an emergency medical condition de-  
34 scribed in subparagraph (A)(i)—

35 “(I) a medical screening examination (as required  
36 under section 1867 of the Social Security Act) that is  
37 within the capability of the emergency department of a  
38 hospital, including ancillary services routinely available  
39 to the emergency department to evaluate such emergency  
40 medical condition, and

1 “(II) within the capabilities of the staff and facili-  
2 ties available at the hospital, such further medical exam-  
3 ination and treatment as are required under section  
4 1867 of such Act to stabilize the patient; or

5 “(ii) with respect to an emergency medical condition de-  
6 scribed in subparagraph (A)(ii), medical treatment for such  
7 condition rendered by a health care provider in a hospital to  
8 a neonate, including available hospital ancillary services in re-  
9 sponse to an urgent request of a health care professional and  
10 to the extent necessary to stabilize the neonate.

11 “(C) STABILIZE.—The term ‘to stabilize’ means, with respect  
12 to an emergency medical condition, to provide such medical treat-  
13 ment of the condition as may be necessary to assure, within rea-  
14 sonable medical probability, that no material deterioration of the  
15 condition is likely to result from or occur during the transfer of  
16 the individual from a facility.

17 “(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STA-  
18 BILIZATION CARE.—If benefits are available under a group health plan, or  
19 under health insurance coverage offered by a health insurance issuer in con-  
20 nection with such a plan, with respect to maintenance care or post-stabiliza-  
21 tion care covered under the guidelines established under section 1852(d)(2)  
22 of the Social Security Act, the plan or issuer shall provide for reimburse-  
23 ment with respect to such services provided to a participant or beneficiary  
24 other than through a participating health care provider in a manner con-  
25 sistent with subsection (a)(1)(C) (and shall otherwise comply with such  
26 guidelines).

27 “(c) COVERAGE OF EMERGENCY AMBULANCE SERVICES.—

28 “(1) IN GENERAL.—If a group health plan, or health insurance  
29 coverage provided by a health insurance issuer in connection with such  
30 a plan, provides any benefits with respect to ambulance services and  
31 emergency services, the plan or issuer shall cover emergency ambulance  
32 services (as defined in paragraph (2))) furnished under the plan or cov-  
33 erage under the same terms and conditions under subparagraphs (A)  
34 through (D) of subsection (a)(1) under which coverage is provided for  
35 emergency services.

36 “(2) EMERGENCY AMBULANCE SERVICES.—For purposes of this  
37 subsection, the term ‘emergency ambulance services’ means ambulance  
38 services (as defined for purposes of section 1861(s)(7) of the Social Se-  
39 curity Act) furnished to transport an individual who has an emergency  
40 medical condition (as defined in subsection (a)(2)(A)) to a hospital for  
41 the receipt of emergency services (as defined in subsection (a)(2)(B))

1 in a case in which the emergency services are covered under the plan  
2 or coverage pursuant to subsection (a)(1) and a prudent layperson,  
3 with an average knowledge of health and medicine, could reasonably ex-  
4 pect that the absence of such transport would result in placing the  
5 health of the individual in serious jeopardy, serious impairment of bod-  
6 ily function, or serious dysfunction of any bodily organ or part.

7 **“SEC. 814. ACCESS TO SPECIALTY CARE.**

8 “(a) SPECIALTY CARE FOR COVERED SERVICES.—

9 “(1) IN GENERAL.—If—

10 “(A) an individual is a participant or beneficiary under a  
11 group health plan or is covered under health insurance coverage  
12 offered by a health insurance issuer in connection with such a  
13 plan,

14 “(B) the individual has a condition or disease of sufficient se-  
15 riousness and complexity to require treatment by a specialist or  
16 the individual requires physician pathology services, and

17 “(C) benefits for such treatment or services are provided  
18 under the plan or coverage,

19 the plan or issuer shall make or provide for a referral to a specialist  
20 who is available and accessible (consistent with standards developed  
21 under section 818) to provide the treatment for such condition or dis-  
22 ease or to provide such services.

23 “(2) SPECIALIST DEFINED.—For purposes of this subsection, the  
24 term ‘specialist’ means, with respect to a condition or services, a health  
25 care practitioner, facility, or center or physician pathologist that has  
26 adequate expertise through appropriate training and experience (includ-  
27 ing, in the case of a child, appropriate pediatric expertise and in the  
28 case of a pregnant woman, appropriate obstetrical expertise) to provide  
29 high quality care in treating the condition or to provide physician pa-  
30 thology services.

31 “(3) CARE UNDER REFERRAL.—A group health plan or health in-  
32 surance issuer may require that the care provided to an individual pur-  
33 suant to such referral under paragraph (1) with respect to treatment  
34 be—

35 “(A) pursuant to a treatment plan, only if the treatment plan  
36 is developed by the specialist and approved by the plan or issuer,  
37 in consultation with the designated primary care provider or spe-  
38 cialist and the individual (or the individual’s designee), and

39 “(B) in accordance with applicable quality assurance and uti-  
40 lization review standards of the plan or issuer.



1 Nothing in this subsection shall be construed as preventing such a  
2 treatment plan for an individual from requiring a specialist to provide  
3 the primary care provider with regular updates on the specialty care  
4 provided, as well as all necessary medical information.

5 “(4) REFERRALS TO PARTICIPATING PROVIDERS.—A group health  
6 plan or health insurance issuer is not required under paragraph (1) to  
7 provide for a referral to a specialist that is not a participating provider,  
8 unless the plan or issuer does not have a specialist that is available and  
9 accessible to treat the individual’s condition or provide physician pa-  
10 thology services and that is a participating provider with respect to  
11 such treatment or services.

12 “(5) REFERRALS TO NONPARTICIPATING PROVIDERS.—In a case  
13 in which a referral of an individual to a nonparticipating specialist is  
14 required under paragraph (1), the group health plan or health insur-  
15 ance issuer shall provide the individual the option of at least three non-  
16 participating specialists.

17 “(6) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan  
18 or issuer refers an individual to a nonparticipating specialist pursuant  
19 to paragraph (1), services provided pursuant to the approved treatment  
20 plan (if any) shall be provided at no additional cost to the individual  
21 beyond what the individual would otherwise pay for services received  
22 by such a specialist that is a participating provider.

23 “(b) SPECIALISTS AS GATEKEEPER FOR TREATMENT OF ONGOING  
24 SPECIAL CONDITIONS.—

25 “(1) IN GENERAL.—A group health plan, or a health insurance  
26 issuer, in connection with the provision of health insurance coverage in  
27 connection with such a plan, shall have a procedure by which an indi-  
28 vidual who is a participant or beneficiary and who has an ongoing spe-  
29 cial condition (as defined in paragraph (3)) may request and receive  
30 a referral to a specialist for such condition who shall be responsible for  
31 and capable of providing and coordinating the individual’s care with re-  
32 spect to the condition. Under such procedures if such an individual’s  
33 care would most appropriately be coordinated by such a specialist, such  
34 plan or issuer shall refer the individual to such specialist.

35 “(2) TREATMENT FOR RELATED REFERRALS.—Such specialists  
36 shall be permitted to treat the individual without a referral from the  
37 individual’s primary care provider and may authorize such referrals,  
38 procedures, tests, and other medical services as the individual’s primary  
39 care provider would otherwise be permitted to provide or authorize,  
40 subject to the terms of the treatment (referred to in subsection  
41 (a)(3)(A)) with respect to the ongoing special condition.

1           “(3) ONGOING SPECIAL CONDITION DEFINED.—In this subsection,  
2           the term ‘ongoing special condition’ means a condition or disease  
3           that—

4                     “(A) is life-threatening, degenerative, or disabling, and

5                     “(B) requires specialized medical care over a prolonged period  
6           of time.

7           “(4) TERMS OF REFERRAL.—The provisions of paragraphs (3)  
8           through (5) of subsection (a) apply with respect to referrals under  
9           paragraph (1) of this subsection in the same manner as they apply to  
10          referrals under subsection (a)(1).

11          “(5) CONSTRUCTION.—Nothing in this subsection shall be con-  
12          strued as preventing an individual who is a participant or beneficiary  
13          and who has an ongoing special condition from having the individual’s  
14          primary care physician assume the responsibilities for providing and co-  
15          ordinating care described in paragraph (1).

16          “(c) STANDING REFERRALS.—

17                 “(1) IN GENERAL.—A group health plan, and a health insurance  
18                 issuer in connection with the provision of health insurance coverage in  
19                 connection with such a plan, shall have a procedure by which an indi-  
20                 vidual who is a participant or beneficiary and who has a condition that  
21                 requires ongoing care from a specialist may receive a standing referral  
22                 to such specialist for treatment of such condition. If the plan or issuer,  
23                 or if the primary care provider in consultation with the medical director  
24                 of the plan or issuer and the specialist (if any), determines that such  
25                 a standing referral is appropriate, the plan or issuer shall make such  
26                 a referral to such a specialist if the individual so desires.

27                 “(2) TERMS OF REFERRAL.—The provisions of paragraphs (3)  
28                 through (5) of subsection (a) apply with respect to referrals under  
29                 paragraph (1) of this subsection in the same manner as they apply to  
30                 referrals under subsection (a)(1).

31          **“SEC. 815. ACCESS TO OBSTETRICAL AND GYNECOLOGICAL CARE.**

32                 “(a) IN GENERAL.—If a group health plan, or a health insurance  
33                 issuer in connection with the provision of health insurance coverage in con-  
34                 nection with such a plan, requires or provides for a participant or bene-  
35                 ficiary to designate a participating primary care health care professional,  
36                 the plan or issuer—

37                     “(1) may not require authorization or a referral by the individual’s  
38                     primary care health care professional or otherwise for covered gyneco-  
39                     logical care (including preventive women’s health examinations) or for  
40                     covered pregnancy-related services provided by a participating physician  
41                     (including a family practice physician) who specializes or is trained and

1 experienced in gynecology or obstetrics, respectively, to the extent such  
2 care is otherwise covered; and

3 “(2) shall treat the ordering of other gynecological or obstetrical  
4 care by such a participating physician as the authorization of the pri-  
5 mary care health care professional with respect to such care under the  
6 plan or coverage.

7 “(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed  
8 to—

9 “(1) waive any exclusions of coverage under the terms of the plan  
10 with respect to coverage of gynecological or obstetrical care;

11 “(2) preclude the group health plan or health insurance issuer in-  
12 volved from requiring that the gynecologist or obstetrician notify the  
13 primary care health care professional or the plan of treatment deci-  
14 sions; or

15 “(3) prevent a plan or issuer from offering, in addition to physi-  
16 cians described in subsection (a)(1), non-physician health care profes-  
17 sionals who are trained and experienced in gynecology or obstetrics.

18 **“SEC. 816. ACCESS TO PEDIATRIC CARE.**

19 “(a) PEDIATRIC CARE.—If a group health plan, or a health insurance  
20 issuer in connection with the provision of health insurance coverage in con-  
21 nection with such a plan, requires or provides for a participant or bene-  
22 ficiary to designate a participating primary care provider for a child of such  
23 individual, the plan or issuer shall permit the participant or beneficiary to  
24 designate a physician (including a family practice physician) who specializes  
25 or is trained and experienced in pediatrics as the child’s primary care pro-  
26 vider.

27 “(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed to  
28 waive any exclusions of coverage under the terms of the plan with respect  
29 to coverage of pediatric care.

30 **“SEC. 817. CONTINUITY OF CARE.**

31 “(a) IN GENERAL.—

32 “(1) TERMINATION OF PROVIDER.—If a contract between a group  
33 health plan, or a health insurance issuer in connection with the provi-  
34 sion of health insurance coverage in connection with such a plan, and  
35 a health care provider is terminated (as defined in paragraph (3)(B)),  
36 or benefits or coverage provided by a health care provider are termi-  
37 nated because of a change in the terms of provider participation in a  
38 group health plan, and an individual who is a participant or beneficiary  
39 in the plan or coverage is undergoing treatment from the provider for  
40 an ongoing special condition (as defined in paragraph (3)(A)) at the  
41 time of such termination, the plan or issuer shall—

1 “(A) notify the individual on a timely basis of such termi-  
2 nation and of the right to elect continuation of coverage of treat-  
3 ment by the provider under this section; and

4 “(B) subject to subsection (c), permit the individual to elect  
5 to continue to be covered with respect to treatment by the provider  
6 of such condition during a transitional period (provided under sub-  
7 section (b)).

8 “(2) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH  
9 INSURANCE ISSUER.—If a contract for the provision of health insur-  
10 ance coverage between a group health plan and a health insurance  
11 issuer is terminated and, as a result of such termination, coverage of  
12 services of a health care provider is terminated with respect to an indi-  
13 vidual, the provisions of paragraph (1) (and the succeeding provisions  
14 of this section) shall apply under the plan in the same manner as if  
15 there had been a contract between the plan and the provider that had  
16 been terminated, but only with respect to benefits that are covered  
17 under the plan after the contract termination.

18 “(3) DEFINITIONS.—For purposes of this section:

19 “(A) ONGOING SPECIAL CONDITION.—The term ‘ongoing spe-  
20 cial condition’ has the meaning given such term in section  
21 814(b)(3), and also includes pregnancy.

22 “(B) TERMINATION.—The term ‘terminated’ includes, with  
23 respect to a contract, the expiration or nonrenewal of the contract,  
24 but does not include a termination of the contract by the plan or  
25 issuer for failure to meet applicable quality standards or for fraud.

26 “(b) TRANSITIONAL PERIOD.—

27 “(1) IN GENERAL.—Except as provided in paragraphs (2) through  
28 (4), the transitional period under this subsection shall extend up to 90  
29 days (as determined by the treating health care professional) after the  
30 date of the notice described in subsection (a)(1)(A) of the provider’s  
31 termination.

32 “(2) SCHEDULED SURGERY AND ORGAN TRANSPLANTATION.—If  
33 surgery or organ transplantation was scheduled for an individual before  
34 the date of the announcement of the termination of the provider status  
35 under subsection (a)(1)(A) or if the individual on such date was on an  
36 established waiting list or otherwise scheduled to have such surgery or  
37 transplantation, the transitional period under this subsection with re-  
38 spect to the surgery or transplantation shall extend beyond the period  
39 under paragraph (1) and until the date of discharge of the individual  
40 after completion of the surgery or transplantation.

41 “(3) PREGNANCY.—If—

1           “(A) a participant or beneficiary was determined to be preg-  
2           nant at the time of a provider’s termination of participation, and

3           “(B) the provider was treating the pregnancy before date of  
4           the termination,

5           the transitional period under this subsection with respect to provider’s  
6           treatment of the pregnancy shall extend through the provision of post-  
7           partum care directly related to the delivery.

8           “(4) TERMINAL ILLNESS.—If—

9           “(A) a participant or beneficiary was determined to be termi-  
10          nally ill (as determined under section 1861(dd)(3)(A) of the Social  
11          Security Act) at the time of a provider’s termination of participa-  
12          tion, and

13          “(B) the provider was treating the terminal illness before the  
14          date of termination,

15          the transitional period under this subsection shall extend for the re-  
16          mainder of the individual’s life for care directly related to the treat-  
17          ment of the terminal illness or its medical manifestations.

18          “(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan or  
19          health insurance issuer may condition coverage of continued treatment by  
20          a provider under subsection (a)(1)(B) upon the individual notifying the plan  
21          of the election of continued coverage and upon the provider agreeing to the  
22          following terms and conditions:

23               “(1) The provider agrees to accept reimbursement from the plan  
24               or issuer and individual involved (with respect to cost-sharing) at the  
25               rates applicable prior to the start of the transitional period as payment  
26               in full (or, in the case described in subsection (a)(2), at the rates appli-  
27               cable under the replacement plan or issuer after the date of the termi-  
28               nation of the contract with the health insurance issuer) and not to im-  
29               pose cost-sharing with respect to the individual in an amount that  
30               would exceed the cost-sharing that could have been imposed if the con-  
31               tract referred to in subsection (a)(1) had not been terminated.

32               “(2) The provider agrees to adhere to the quality assurance stand-  
33               ards of the plan or issuer responsible for payment under paragraph (1)  
34               and to provide to such plan or issuer necessary medical information re-  
35               lated to the care provided.

36               “(3) The provider agrees otherwise to adhere to such plan’s or  
37               issuer’s policies and procedures, including procedures regarding refer-  
38               rals and obtaining prior authorization and providing services pursuant  
39               to a treatment plan (if any) approved by the plan or issuer.

1       “(d) CONSTRUCTION.—Nothing in this section shall be construed to re-  
2       quire the coverage of benefits which would not have been covered if the pro-  
3       vider involved remained a participating provider.

4       **“SEC. 818. NETWORK ADEQUACY.**

5       “(a) REQUIREMENT.—A group health plan, and a health insurance  
6       issuer providing health insurance coverage in connection with such a plan,  
7       shall meet such standards for network adequacy as are established by law  
8       pursuant to this section.

9       “(b) DEVELOPMENT OF STANDARDS.—

10       “(1) ESTABLISHMENT OF PANEL.—There is established a panel to  
11       be known as the Health Care Panel to Establish Network Adequacy  
12       Standards (in this section referred to as the ‘Panel’).

13       “(2) DUTIES OF PANEL.—The Panel shall devise standards for  
14       group health plans and health insurance issuers that offer health insur-  
15       ance coverage in connection with such a plan to ensure that—

16               “(A) participants and beneficiaries have access to a sufficient  
17               number, mix, and distribution of health care professionals and  
18               providers; and

19               “(B) covered items and services are available and accessible  
20               to each participant and beneficiary—

21                       “(i) in the service area of the plan or issuer;

22                       “(ii) at a variety of sites of service;

23                       “(iii) with reasonable promptness (including reasonable  
24                       hours of operation and after hours services);

25                       “(iv) with reasonable proximity to the residences or  
26                       workplaces of participants and beneficiaries; and

27                       “(v) in a manner that takes into account the diverse  
28                       needs of such individuals and reasonably assures continuity of  
29                       care.

30       “(c) MEMBERSHIP.—

31       “(1) SIZE AND COMPOSITION.—The Panel shall be composed of 15  
32       members. The Secretary of Health and Human Services, the Majority  
33       Leader of the Senate, and the Speaker of House of Representatives  
34       shall each appoint 1 member from representatives of private insurance  
35       organizations, consumer groups, State insurance commissioners, State  
36       medical societies, and State medical specialty societies.

37       “(2) TERMS OF APPOINTMENT.—The members of the Panel shall  
38       serve for the life of the Panel.

39       “(3) VACANCIES.—A vacancy in the Panel shall not affect the  
40       power of the remaining members to execute the duties of the Panel,

1 but any such vacancy shall be filled in the same manner in which the  
2 original appointment was made.

3 “(d) PROCEDURES.—

4 “(1) MEETINGS.—The Panel shall meet at the call of a majority  
5 of its members.

6 “(2) FIRST MEETING.—The Panel shall convene not later than 60  
7 days after the date of the enactment of the Health Care Quality and  
8 Choice Act of 1999.

9 “(3) QUORUM.—A quorum shall consist of a majority of the mem-  
10 bers of the Panel.

11 “(4) HEARINGS.—For the purpose of carrying out its duties, the  
12 Panel may hold such hearings and undertake such other activities as  
13 the Panel determines to be necessary to carry out its duties.

14 “(e) ADMINISTRATION.—

15 “(1) COMPENSATION.—Except as provided in paragraph (1),  
16 members of the Panel shall receive no additional pay, allowances, or  
17 benefits by reason of their service on the Panel.

18 “(2) TRAVEL EXPENSES AND PER DIEM.—Each member of the  
19 Panel who is not an officer or employee of the Federal Government  
20 shall receive travel expenses and per diem in lieu of subsistence in ac-  
21 cordance with sections 5702 and 5703 of title 5, United States Code.

22 “(3) CONTRACT AUTHORITY.—The Panel may contract with and  
23 compensate government and private agencies or persons for items and  
24 services, without regard to section 3709 of the Revised Statutes (41  
25 U.S.C. 5).

26 “(4) USE OF MAILS.—The Panel may use the United States mails  
27 in the same manner and under the same conditions as Federal agencies  
28 and shall, for purposes of the frank, be considered a commission of  
29 Congress as described in section 3215 of title 39, United States Code.

30 “(5) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of  
31 the Panel, the Secretary of Health and Human Services shall provide  
32 to the Panel on a reimbursable basis such administrative support serv-  
33 ices as the Panel may request.

34 “(f) REPORT AND ESTABLISHMENT OF STANDARDS.—Not later than  
35 2 years after the first meeting, the Panel shall submit a report to Congress  
36 and the Secretary of Health and Human Services detailing the standards  
37 devised under subsection (b) and recommendations regarding the implemen-  
38 tation of such standards. Such standards shall take effect to the extent pro-  
39 vided by Federal law enacted after the date of the submission of such re-  
40 port.

1 “(g) TERMINATION.—The Panel shall terminate on the day after sub-  
2 mitting its report to the Secretary of Health and Human Services under  
3 subsection (f).

4 **“SEC. 819. ACCESS TO EXPERIMENTAL OR INVESTIGATIONAL PRE-**  
5 **SCRIPTION DRUGS.**

6 “No use of a prescription drug or medical device shall be considered  
7 experimental or investigational under a group health plan or under health  
8 insurance coverage provided by a health insurance issuer in connection with  
9 such a plan if such use is included in the labeling authorized by the U.S.  
10 Food and Drug Administration under section 505, 513 or 515 of the Fed-  
11 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355) or under section 351  
12 of the Public Health Service Act (42 U.S.C. 262), unless such use is dem-  
13 onstrated to be unsafe or ineffective.

14 **“SEC. 820. COVERAGE FOR INDIVIDUALS PARTICIPATING IN AP-**  
15 **PROVED CANCER CLINICAL TRIALS.**

16 “(a) COVERAGE.—

17 “(1) IN GENERAL.—If a group health plan (or a health insurance  
18 issuer offering health insurance coverage in connection with such a  
19 plan) provides coverage to a qualified individual (as defined in sub-  
20 section (b)), the plan or issuer—

21 “(A) may not deny the individual participation in the clinical  
22 trial referred to in subsection (b)(2);

23 “(B) subject to subsections (b), (c), and (d), may not deny  
24 (or limit or impose additional conditions on) the coverage of rou-  
25 tine patient costs for items and services furnished in connection  
26 with participation in the trial; and

27 “(C) may not discriminate against the individual on the basis  
28 of the individual’s participation in such trial.

29 “(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph  
30 (1)(B), routine patient costs do not include the cost of the tests or  
31 measurements conducted primarily for the purpose of the clinical trial  
32 involved.

33 “(3) USE OF IN-NETWORK PROVIDERS.—If one or more partici-  
34 pating providers is participating in a clinical trial, nothing in para-  
35 graph (1) shall be construed as preventing a plan or issuer from requir-  
36 ing that a qualified individual participate in the trial through such a  
37 participating provider if the provider will accept the individual as a par-  
38 ticipant in the trial.

39 “(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection  
40 (a), the term ‘qualified individual’ means an individual who is a participant  
41 or beneficiary in a group health plan who meets the following conditions:

42 “(1)(A) The individual has been diagnosed with cancer.



1           “(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

2           “(C) The individual’s participation in the trial offers meaningful potential for significant clinical benefit for the individual.

3           “(2) Either—

4               “(A) the referring physician is a participating health care professional and has concluded that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

5               “(B) the individual provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

6           “(c) PAYMENT.—

7               “(1) IN GENERAL.—Under this section a group health plan (or health insurance issuer offering health insurance) shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

8               “(2) ROUTINE PATIENT CARE COSTS.—For purposes of this section—

9               “(A) IN GENERAL.—The term ‘routine patient care costs’ includes the costs associated with the provision of items and services that—

10               “(i) would otherwise be covered under the group health plan if such items and services were not provided in connection with an approved clinical trial program; and

11               “(ii) are furnished according to the protocol of an approved clinical trial program.

12               “(B) EXCLUSION.—Such term does include the costs associated with the provision of—

13               “(i) an investigational drug or device, unless the Secretary has authorized the manufacturer of such drug or device to charge for such drug or device; or

14               “(ii) any item or service supplied without charge by the sponsor of the approved clinical trial program.

15               “(3) PAYMENT RATE.—In the case of covered items and services provided by—

16               “(A) a participating provider, the payment rate shall be at the agreed upon rate, or

1 “(B) a nonparticipating provider, the payment rate shall be  
2 at the rate the plan or issuer would normally pay for comparable  
3 items or services under subparagraph (A).

4 “(d) APPROVED CLINICAL TRIAL DEFINED.—In this section, the term  
5 ‘approved clinical trial’ means a cancer clinical research study or cancer  
6 clinical investigation approved by an Institutional Review Board.

7 “(e) CONSTRUCTION.—Nothing in this section shall be construed to  
8 limit a plan’s or issuer’s coverage with respect to clinical trials.

9 “(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBIL-  
10 ITIES OF FIDUCIARIES.—

11 “(1) IN GENERAL.—For purposes of this section, insofar as a  
12 group health plan provides benefits in the form of health insurance cov-  
13 erage through a health insurance issuer, the plan shall be treated as  
14 meeting the requirements of this section with respect to such benefits  
15 and not be considered as failing to meet such requirements because of  
16 a failure of the issuer to meet such requirements so long as the plan  
17 sponsor or its representatives did not cause such failure by the issuer.

18 “(2) CONSTRUCTION.—Nothing in this section shall be construed  
19 to affect or modify the responsibilities of the fiduciaries of a group  
20 health plan under part 4 of subtitle B.

21 “SUBPART C—ACCESS TO INFORMATION

22 **“SEC. 821. PATIENT ACCESS TO INFORMATION.**

23 “(a) DISCLOSURE REQUIREMENT.—

24 “(1) GROUP HEALTH PLANS.—A group health plan shall—

25 “(A) provide to participants and beneficiaries at the time of  
26 initial coverage under the plan (or the effective date of this sec-  
27 tion, in the case of individuals who are participants or bene-  
28 ficiaries as of such date), and at least annually thereafter, the in-  
29 formation described in subsection (b);

30 “(B) provide to participants and beneficiaries, within a rea-  
31 sonable period (as specified by the Secretary) before or after the  
32 date of significant changes in the information described in sub-  
33 section (b), information on such significant changes; and

34 “(C) upon request, make available to participants and bene-  
35 ficiaries, the Secretary, and prospective participants and bene-  
36 ficiaries, the information described in subsection (b) or (c).

37 The plan may charge a reasonable fee for provision in printed form of  
38 any of the information described in subsection (b) or (c) more than  
39 once during any plan year.

1           “(2) HEALTH INSURANCE ISSUERS.—A health insurance issuer in  
2 connection with the provision of health insurance coverage in connec-  
3 tion with a group health plan shall—

4           “(A) provide to participants and beneficiaries enrolled under  
5 such coverage at the time of enrollment, and at least annually  
6 thereafter, the information described in subsection (b);

7           “(B) provide to such participants and beneficiaries, within a  
8 reasonable period (as specified by the Secretary) before or after  
9 the date of significant changes in the information described in  
10 subsection (b), information in printed form on such significant  
11 changes; and

12           “(C) upon request, make available to the Secretary, to indi-  
13 viduals who are prospective participants and beneficiaries, and to  
14 the public the information described in subsection (b) or (c).

15           “(3) EMPLOYERS.—Effective 5 years after the date this part first  
16 becomes effective, each employer (other than an employer described in  
17 paragraph (1) of subsection (d)) shall provide to each employee at least  
18 annually information (consistent with such subsection) on the amount  
19 that the employer contributes on behalf of the employee (and any de-  
20 pendants of the employee) for health benefits coverage.

21           “(b) INFORMATION PROVIDED.—The information described in this sub-  
22 section with respect to a group health plan or health insurance coverage of-  
23 fered by a health insurance issuer shall be provided to a participant or bene-  
24 ficiary free of charge at least once a year and includes the following:

25           “(1) SERVICE AREA.—The service area of the plan or issuer.

26           “(2) BENEFITS.—Benefits offered under the plan or coverage,  
27 including—

28           “(A) those that are covered benefits “(all of which shall be  
29 referred to by such relevant CPT and DRG codes as are avail-  
30 able), limits and conditions on such benefits, and those benefits  
31 that are explicitly excluded from coverage (all of which shall be re-  
32 ferred to by such relevant CPT and DRG codes as are available);

33           “(B) cost sharing, such as deductibles, coinsurance, and co-  
34 payment amounts, including any liability for balance billing, any  
35 maximum limitations on out of pocket expenses, and the maximum  
36 out of pocket costs for services that are provided by nonpartici-  
37 pating providers or that are furnished without meeting the appli-  
38 cable utilization review requirements;

39           “(C) the extent to which benefits may be obtained from non-  
40 participating providers;

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1 “(D) the extent to which a participant or beneficiary may se-  
2 lect from among participating providers and the types of providers  
3 participating in the plan or issuer network;

4 “(E) process for determining experimental coverage; and

5 “(F) use of a prescription drug formulary.

6 “(3) ACCESS.—A description of the following:

7 “(A) The number, mix, and distribution of providers under  
8 the plan or coverage.

9 “(B) Out-of-network coverage (if any) provided by the plan  
10 or coverage.

11 “(C) Any point-of-service option (including any supplemental  
12 premium or cost-sharing for such option).

13 “(D) The procedures for participants and beneficiaries to se-  
14 lect, access, and change participating primary and specialty pro-  
15 viders.

16 “(E) The rights and procedures for obtaining referrals (in-  
17 cluding standing referrals) to participating and nonparticipating  
18 providers.

19 “(F) The name, address, and telephone number of partici-  
20 pating health care providers and an indication of whether each  
21 such provider is available to accept new patients.

22 “(G) Any limitations imposed on the selection of qualifying  
23 participating health care providers, including any limitations im-  
24 posed under section 812(b)(2).

25 “(4) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by  
26 the plan or issuer.

27 “(5) EMERGENCY COVERAGE.—Coverage of emergency services,  
28 including—

29 “(A) the appropriate use of emergency services, including use  
30 of the 911 telephone system or its local equivalent in emergency  
31 situations and an explanation of what constitutes an emergency  
32 situation;

33 “(B) the process and procedures of the plan or issuer for ob-  
34 taining emergency services; and

35 “(C) the locations of (i) emergency departments, and (ii)  
36 other settings, in which plan physicians and hospitals provide  
37 emergency services and post-stabilization care.

38 “(6) PRIOR AUTHORIZATION RULES.—Rules regarding prior au-  
39 thorization or other review requirements that could result in noncov-  
40 erage or nonpayment.

1           “(7) GRIEVANCE AND APPEALS PROCEDURES.—All appeal or  
2 grievance rights and procedures under the plan or coverage, including  
3 the method for filing grievances and the time frames and circumstances  
4 for acting on grievances and appeals, who is the applicable authority  
5 with respect to the plan or issuer.

6           “(8) ACCOUNTABILITY.—A description of the legal recourse op-  
7 tions available for participants and beneficiaries under the plan  
8 including—

9           “(A) the preemption that applies under section 514 to certain  
10 actions arising out of the provision of health benefits; and

11           “(B) the extent to which coverage decisions made by the plan  
12 are subject to internal review or any external review and the prop-  
13 er time frames under

14           “(9) QUALITY ASSURANCE.—Any information made public by an  
15 accrediting organization in the process of accreditation of the plan or  
16 issuer or any additional quality indicators the plan or issuer makes  
17 available.

18           “(10) INFORMATION ON ISSUER.—Notice of appropriate mailing  
19 addresses and telephone numbers to be used by participants and bene-  
20 ficiaries in seeking information or authorization for treatment.

21           “(11) AVAILABILITY OF INFORMATION ON REQUEST.—Notice that  
22 the information described in subsection (c) is available upon request.

23           “(c) INFORMATION MADE AVAILABLE UPON REQUEST.—The informa-  
24 tion described in this subsection is the following:

25           “(1) UTILIZATION REVIEW ACTIVITIES.—A description of proce-  
26 dures used and requirements (including circumstances, time frames,  
27 and appeal rights) under any utilization review program under section  
28 801.

29           “(2) GRIEVANCE AND APPEALS INFORMATION.—Information on  
30 the number of grievances and appeals and on the disposition in the ag-  
31 gregate of such matters.

32           “(3) FORMULARY RESTRICTIONS.—A description of the nature of  
33 any drug formula restrictions.

34           “(4) PARTICIPATING PROVIDER LIST.—A list of current partici-  
35 pating health care providers.

36           “(d) EMPLOYER INFORMATION.—

37           “(1) SMALL EMPLOYER EXEMPTION.—Subsection (a)(3) shall not  
38 apply to an employer that is a small employer (as defined in section  
39 712(c)(1)(B)) or would be such an employer if ‘100’ were substituted  
40 for ‘50’ in such section.

1           “(2) COMPUTATION.—The amount described in subsection (a)(3)  
2           may be computed on an average, per employee basis, and may be based  
3           on rules similar to the rules applied in computing the applicable pre-  
4           mium under section 604.

5           “(3) FORM OF DISCLOSURE.—The information under subsection  
6           (a)(3) may be provided in any reasonable form, including as part of  
7           the summary plan description, a letter, or information accompanying  
8           a W-2 form.

9           “(e) CONSTRUCTION.—Nothing in this section shall be construed as re-  
10          quiring public disclosure of individual contracts or financial arrangements  
11          between a group health plan or health insurance issuer and any provider.

12          “SUBPART D—PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

13          **“SEC. 831. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL**  
14          **COMMUNICATIONS.**

15          “(a) GENERAL RULE.—The provisions of any contract or agreement,  
16          or the operation of any contract or agreement, between a group health plan  
17          or health insurance issuer in relation to health insurance coverage offered  
18          in connection with such a plan (including any partnership, association, or  
19          other organization that enters into or administers such a contract or agree-  
20          ment) and a health care provider (or group of health care providers) shall  
21          not prohibit or otherwise restrict a health care professional from advising  
22          such a participant or beneficiary who is a patient of the professional about  
23          the health status of the individual or medical care or treatment for the indi-  
24          vidual’s condition or disease, regardless of whether benefits for such care  
25          or treatment are provided under the plan or coverage, if the professional  
26          is acting within the lawful scope of practice.

27          “(b) NULLIFICATION.—Any contract provision or agreement that re-  
28          stricts or prohibits medical communications in violation of subsection (a)  
29          shall be null and void.

30          **“SEC. 832. PROHIBITION OF DISCRIMINATION AGAINST PROVIDERS**  
31          **BASED ON LICENSURE.**

32          “(a) IN GENERAL.—A group health plan and a health insurance issuer  
33          offering health insurance coverage in connection with such a plan shall not  
34          discriminate with respect to participation or indemnification as to any pro-  
35          vider who is acting within the scope of the provider’s license or certification  
36          under applicable State law, solely on the basis of such license or certifi-  
37          cation.

38          “(b) CONSTRUCTION.—Subsection (a) shall not be construed—

39                  “(1) as requiring the coverage under a group health plan or health  
40                  insurance coverage of particular benefits or services or to prohibit a  
41                  plan or issuer from including providers only to the extent necessary to  
42                  meet the needs of the plan’s or issuer’s participants or beneficiaries or

1 from establishing any measure designed to maintain quality and control  
2 costs consistent with the responsibilities of the plan or issuer;

3 “(2) to override any State licensure or scope-of-practice law;

4 “(3) as requiring a plan or issuer that offers network coverage to  
5 include for participation every willing provider who meets the terms  
6 and conditions of the plan or issuer; or

7 “(4) as prohibiting a family practice physician with appropriate  
8 expertise from providing pediatric or obstetrical or gynecological care.

9 **“SEC. 833. PROHIBITION AGAINST IMPROPER INCENTIVE ARRANGE-**  
10 **MENTS.**

11 “(a) IN GENERAL.—A group health plan and a health insurance issuer  
12 offering health insurance coverage in connection with such a plan may not  
13 operate any physician incentive plan (as defined in subparagraph (B) of sec-  
14 tion 1876(i)(8) of the Social Security Act) unless the requirements de-  
15 scribed in clauses (i), (ii)(I), and (iii) of subparagraph (A) of such section  
16 are met with respect to such a plan.

17 “(b) APPLICATION.—For purposes of carrying out paragraph (1), any  
18 reference in section 1876(i)(8) of the Social Security Act to the Secretary,  
19 an eligible organization, or an individual enrolled with the organization shall  
20 be treated as a reference to the applicable authority, a group health plan  
21 or health insurance issuer, respectively, and a participant or beneficiary with  
22 the plan or organization, respectively.

23 “(c) CONSTRUCTION.—Nothing in this section shall be construed as  
24 prohibiting all capitation and similar arrangements or all provider discount  
25 arrangements.

26 **“SEC. 834. PAYMENT OF CLEAN CLAIMS.**

27 “A group health plan, and a health insurance issuer offering group  
28 health insurance coverage, shall provide for prompt payment of claims sub-  
29 mitted for health care services or supplies furnished to a participant or ben-  
30 efiary with respect to benefits covered by the plan or issuer, in a manner  
31 consistent with the provisions of sections 1816(c)(2) and 1842(c)(2) of the  
32 Social Security Act (42 U.S.C. 1395h(c)(2) and 42 U.S.C. 1395u(c)(2)), ex-  
33 cept that for purposes of this section, subparagraph (C) of section  
34 1816(c)(2) of the Social Security Act shall be treated as applying to claims  
35 received from a participant or beneficiary as well as claims referred to in  
36 such subparagraph.

37 **“SUBPART E—DEFINITIONS**

38 **“SEC. 841. DEFINITIONS.**

39 “(a) INCORPORATION OF GENERAL DEFINITIONS.—Except as other-  
40 wise provided, the provisions of section 733 shall apply for purposes of this  
41 part in the same manner as they apply for purposes of part 7.

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1 “(b) ADDITIONAL DEFINITIONS.—For purposes of this part:

2 “(1) APPLICABLE AUTHORITY.—The term ‘applicable authority’  
3 means—

4 “(A) in the case of a group health plan, the Secretary of  
5 Labor; and

6 “(B) in the case of a health insurance issuer with respect to  
7 a specific provision of this part, the applicable State authority (as  
8 defined in section 2791(d) of the Public Health Service Act), or  
9 the Secretary of Health and Human Services, if such Secretary is  
10 enforcing such provision under section 2722(a)(2) or 2761(a)(2)  
11 of the Public Health Service Act.

12 “(2) CLINICAL PEER.—The term ‘clinical peer’ means, with re-  
13 spect to a review or appeal, a practicing physician or other health care  
14 professional who holds a nonrestricted license and who is—

15 “(A) appropriately certified by a nationally recognized, peer  
16 reviewed accrediting body in the same or similar specialty as typi-  
17 cally manages the medical condition, procedure, or treatment  
18 under review or appeal, or

19 “(B) is trained and experienced in managing such condition,  
20 procedure, or treatment,  
21 and includes a pediatric specialist where appropriate; except that only  
22 a physician may be a clinical peer with respect to the review or appeal  
23 of treatment recommended or rendered by a physician.

24 “(3) HEALTH CARE PROFESSIONAL.—The term ‘health care pro-  
25 fessional’ means an individual who is licensed, accredited, or certified  
26 under State law to provide specified health care services and who is op-  
27 erating within the scope of such licensure, accreditation, or certifi-  
28 cation.

29 “(4) HEALTH CARE PROVIDER.—The term ‘health care provider’  
30 includes a physician or other health care professional, as well as an in-  
31 stitutional or other facility or agency that provides health care services  
32 and that is licensed, accredited, or certified to provide health care items  
33 and services under applicable State law.

34 “(5) NETWORK.—The term ‘network’ means, with respect to a  
35 group health plan or health insurance issuer offering health insurance  
36 coverage, the participating health care professionals and providers  
37 through whom the plan or issuer provides health care items and serv-  
38 ices to participants or beneficiaries.

39 “(6) NONPARTICIPATING.—The term ‘nonparticipating’ means,  
40 with respect to a health care provider that provides health care items  
41 and services to a participant or beneficiary under group health plan or



1 health insurance coverage, a health care provider that is not a partici-  
2 pating health care provider with respect to such items and services.

3 “(7) PARTICIPATING.—The term ‘participating’ means, with re-  
4 spect to a health care provider that provides health care items and  
5 services to a participant or beneficiary under group health plan or  
6 health insurance coverage offered by a health insurance issuer in con-  
7 nection with such a plan, a health care provider that furnishes such  
8 items and services under a contract or other arrangement with the plan  
9 or issuer.

10 “(8) PHYSICIAN.—The term ‘physician’ means an allopathic or os-  
11 teopathic physician.

12 “(9) PRACTICING PHYSICIAN.—The term ‘practicing physician’  
13 means a physician who is licensed in the State in which the physician  
14 furnishes professional services and who provides professional services to  
15 individual patients on average at least two full days per week.

16 “(10) PRIOR AUTHORIZATION.—The term ‘prior authorization’  
17 means the process of obtaining prior approval from a health insurance  
18 issuer or group health plan for the provision or coverage of medical  
19 services.

20 **“SEC. 842. RULE OF CONSTRUCTION.**

21 “Nothing in this part or section 714 shall be construed to affect or  
22 modify the provisions of section 514.

23 **“SEC. 843. EXCLUSIONS.**

24 “(a) NO BENEFIT REQUIREMENTS.—Nothing in this part shall be con-  
25 strued to require a group health plan or a health insurance issuer offering  
26 health insurance coverage in connection with such a plan to provide specific  
27 benefits under the terms of such plan or coverage, other than those provided  
28 under the terms of such plan or coverage.

29 “(b) EXCLUSION FOR FEE-FOR-SERVICE COVERAGE.—

30 “(1) IN GENERAL.—

31 “(A) GROUP HEALTH PLANS.—The provisions of sections 811  
32 through 821 shall not apply to a group health plan if the only cov-  
33 erage offered under the plan is fee-for-service coverage (as defined  
34 in paragraph (2)).

35 “(B) HEALTH INSURANCE COVERAGE.—The provisions of sec-  
36 tions 801 through 821 shall not apply to health insurance cov-  
37 erage if the only coverage offered under the coverage is fee-for-  
38 service coverage (as defined in paragraph (2)).

39 “(2) FEE-FOR-SERVICE COVERAGE DEFINED.—For purposes of  
40 this subsection, the term ‘fee-for-service coverage’ means coverage  
41 under a group health plan or health insurance coverage that—

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1 “(A) reimburses hospitals, health professionals, and other  
2 providers on a fee-for-service basis without placing the provider at  
3 financial risk;

4 “(B) does not vary reimbursement for such a provider based  
5 on an agreement to contract terms and conditions or the utiliza-  
6 tion of health care items or services relating to such provider;

7 “(C) allows access to any provider that is lawfully authorized  
8 to provide the covered services and agree to accept the terms and  
9 conditions of payment established under the plan or by the issuer;  
10 and

11 “(D) for which the plan or issuer does not require prior au-  
12 thorization before providing for any health care services.

13 **“SEC. 844. COVERAGE OF LIMITED SCOPE PLANS.**

14 “Only for purposes of applying the requirements of this part under sec-  
15 tion 714, section 733(c)(2)(A) shall be deemed not to apply.

16 **“SEC. 845. REGULATIONS.**

17 “(a) REGULATIONS.—The Secretary of Labor shall issue such regula-  
18 tions as may be necessary or appropriate to carry out this part under sec-  
19 tion 714. The Secretary may promulgate such regulations in the form of  
20 interim final rules as may be necessary to carry out this part in a timely  
21 manner.”.

22 (b) CLERICAL AMENDMENT.—The table of contents in section 1 of the  
23 Employee Retirement Income Security Act of 1974 is amended by inserting  
24 after the item relating to section 734 the following new items:

“PART 8—IMPROVING MANAGED CARE

“SUBPART A—GRIEVANCE AND APPEALS

“Sec. 801. Utilization review activities.

“Sec. 802. Internal appeals procedures.

“Sec. 803. External appeals procedures.

“Sec. 804. Establishment of a grievance process.

“SUBPART B—ACCESS TO CARE

“Sec. 812. Choice of health care professional.

“Sec. 813. Access to emergency care.

“Sec. 814. Access to specialty care.

“Sec. 815. Access to obstetrical and gynecological care.

“Sec. 816. Access to pediatric care.

“Sec. 817. Continuity of care.

“Sec. 818. Network adequacy.

“Sec. 819. Access to experimental or investigational prescription drugs.

“Sec. 820. Coverage for individuals participating in approved cancer clinical trials.

“SUBPART C—ACCESS TO INFORMATION

“Sec. 821. Patient access to information.

“SUBPART D—PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

“Sec. 831. Prohibition of interference with certain medical communications.

“Sec. 832. Prohibition of discrimination against providers based on licensure.

“Sec. 833. Prohibition against improper incentive arrangements.

“Sec. 834. Payment of clean claims.

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## “SUBPART E—DEFINITIONS

“Sec. 841. Definitions.

“Sec. 842. Preemption; State flexibility; construction.

“Sec. 843. Exclusions.

“Sec. 844. Coverage of limited scope plans.

“Sec. 845. Regulations.

1     **SEC. 203. AVAILABILITY OF COURT REMEDIES.**

2           (a) IN GENERAL.—Section 502 of the Employee Retirement Income  
3     Security Act of 1974 (29 U.S.C. 1132) is amended by adding at the end  
4     the following new subsection:

5           “(n) CAUSE OF ACTION RELATING TO PROVISION OF HEALTH BENE-  
6     FITS.—

7           “(1) IN GENERAL.—In any case in which—

8                 “(A) a person who is a fiduciary of a group health plan, a  
9     health insurance issuer offering health insurance coverage in con-  
10    nection with the plan, or an agent of the plan or plan sponsor (not  
11    including a participating physician, other than a physician who  
12    participated in making the final decision under section 802 pursu-  
13    ant to section 802(b)(1)(A)) and who, under the plan, has author-  
14    ity to make final decisions under 802—

15                 “(i) fails to exercise ordinary care in making an incorrect  
16    determination in the case of a participant or beneficiary that  
17    an item or service is excluded from coverage under the terms  
18    of the plan based on the fact that the item or service—

19                 “(I) does not meet the requirements for medical ap-  
20    propriateness or necessity,

21                 “(II) would constitute experimental treatment or  
22    technology (as defined under the plan), or

23                 “(III) is not a covered benefit, or

24                 “(ii) fails to exercise ordinary care to ensure that—

25                         “(I) any denial of claim for benefits (within the  
26    meaning of section 801(f)), or

27                         “(II) any decision by the plan on a request, made  
28    by a participant or beneficiary under section 802 or 803,  
29    for a reversal of an earlier decision of the plan,

30    is made and issued to the participant or beneficiary (in such  
31    form and manner as may be prescribed in regulations of the  
32    Secretary) before the end of the applicable period specified in  
33    section 801, 802, or 803, and

34                 “(B) such failure is the proximate cause of substantial harm  
35    to, or wrongful death of, the participant or beneficiary,  
36    such person shall be liable to the participant or beneficiary (or the es-  
37    tate of such participant or beneficiary) for economic and noneconomic

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1 damages in connection with such failure and such injury or death (sub-  
2 ject to paragraph (10)). For purposes of this subsection, the term ‘final  
3 decision’ means, with respect to a group health plan, the sole final deci-  
4 sion of the plan under section 802.

5 “(2) ORDINARY CARE.—For purposes of this subsection, the term  
6 ‘ordinary care’ means the care, skill, prudence, and diligence under the  
7 circumstances then prevailing that a prudent individual acting in a like  
8 capacity and familiar with such matters would use in the conduct of  
9 an enterprise of a like character and with like aims.

10 “(3) SUBSTANTIAL HARM.—The term ‘substantial harm’ means  
11 loss of life, loss or significant impairment of limb or bodily function,  
12 significant disfigurement, or severe and chronic physical pain.

13 “(4) EXCEPTION FOR EMPLOYERS AND OTHER PLAN SPONSORS.—

14 “(A) IN GENERAL.—Subject to subparagraph (B), paragraph  
15 (1) does not authorize—

16 “(i) any cause of action against an employer or other  
17 plan sponsor maintaining the group health plan (or against  
18 an employee of such an employer or sponsor acting within the  
19 scope of employment),

20 “(ii) a right of recovery or indemnity by a person against  
21 an employer or other plan sponsor (or such an employee) for  
22 damages assessed against the person pursuant to a cause of  
23 action under paragraph (1), or

24 “(iii) any cause of action in connection with the provision  
25 of excepted benefits described in section 733(c), other than  
26 those described in section 733(c)(2).

27 “(B) SPECIAL RULE.—Subparagraph (A) shall not preclude  
28 any cause of action described in paragraph (1) commenced against  
29 an employer or other plan sponsor (or against an employee of such  
30 an employer or sponsor acting within the scope of employment),  
31 but only if—

32 “(i) such action is based on the direct participation of  
33 the employer or other plan sponsor (or employee of the em-  
34 ployer or plan sponsor) in the final decision of the plan with  
35 respect to a specific participant or beneficiary on a claim for  
36 benefits covered under the plan or health insurance coverage  
37 in the case at issue; and

38 “(ii) the decision on the claim resulted in substantial  
39 harm to, or the wrongful death of, such participant or bene-  
40 ficiary.

1           “(C) DIRECT PARTICIPATION.—For purposes of this sub-  
2 section, the term ‘direct participation’ means, in connection with  
3 a final decision under section 802, the actual making of such final  
4 decision as a plan fiduciary or the actual exercise of final control-  
5 ling authority in the approval of such final decision. In deter-  
6 mining whether an employer or other plan sponsor (or employee  
7 of an employer or other plan sponsor) is engaged in direct partici-  
8 pation in the final decision of the plan on a claim, the employer  
9 or plan sponsor (or employee) shall not be construed to be engaged  
10 in such direct participation (and to be liable for any damages  
11 whatsoever) because of any form of decisionmaking or other con-  
12 duct, whether or not fiduciary in nature, that does not involve a  
13 final decision with respect to a specific claim for benefits by a spe-  
14 cific participant or beneficiary, including (but not limited to)—

15           “(i) any participation by the employer or other plan  
16 sponsor (or employee) in the selection of the group health  
17 plan or health insurance coverage involved or the third party  
18 administrator or other agent;

19           “(ii) any engagement by the employer or other plan  
20 sponsor (or employee) in any cost-benefit analysis undertaken  
21 in connection with the selection of, or continued maintenance  
22 of, the plan or coverage involved;

23           “(iii) any participation by the employer or other plan  
24 sponsor (or employee) in the creation, continuation, modifica-  
25 tion, or termination of the plan or of any coverage, benefit,  
26 or item or service covered by the plan;

27           “(iv) any participation by the employer or other plan  
28 sponsor (or employee) in the design of any coverage, benefit,  
29 or item or service covered by the plan, including the amount  
30 of copayment and limits connected with such coverage, and  
31 the specification of any protocol, procedure, or policy for de-  
32 termining whether any such coverage, benefit, or item or serv-  
33 ice is medically necessary and appropriate or is experimental  
34 or investigational;

35           “(v) any action by an agent of the employer or plan  
36 sponsor in making such a final decision on behalf of such em-  
37 ployer or plan sponsor;

38           “(vi) any decision by an employer or plan sponsor (or  
39 employee) or agent acting on behalf of an employer or plan  
40 sponsor either to authorize coverage for, or to intercede or  
41 not to intercede as an advocate for or on behalf of, any spe-

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cific participant or beneficiary (or group of participants or beneficiaries) under the plan;

“(vii) the approval of, or participation in the approval of, the plan provisions defining medical necessity or of policies or procedures that have a direct bearing on the outcome of the final decision; or

“(viii) any other form of decisionmaking or other conduct performed by the employer or other plan sponsor (or employee) in connection with the plan or coverage involved unless it involves the making of a final decision of the plan consisting of a failure described in clause (i) or (ii) of paragraph (1)(A) as to specific participants or beneficiaries who suffer substantial harm or wrongful death as a proximate cause of such decision.

“(5) REQUIRED DEMONSTRATION OF DIRECT PARTICIPATION.—An action against an employer or plan sponsor (or employee thereof) under this subsection shall be immediately dismissed—

“(A) in the absence of an allegation in the complaint of direct participation by the employer or plan sponsor in the final decision of the plan with respect to a specific participant or beneficiary who suffers substantial harm or wrongful death, or

“(B) upon a demonstration to the court that such employer or plan sponsor (or employee) did not directly participate in the final decision of the plan.

“(6) TREATMENT OF THIRD-PARTY PROVIDERS OF NONDISCRETIONARY ADMINISTRATIVE SERVICES.—Paragraph (1) does not authorize any action against any person providing nondiscretionary administrative services to employers or other plan sponsors.

“(7) REQUIREMENT OF EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

“(A) IN GENERAL.—Paragraph (1) applies in the case of any cause of action only if all remedies under section 503 (including remedies under sections 802 and 803, made applicable under section 714) with respect to such cause of action have been exhausted.

“(B) EXTERNAL REVIEW REQUIRED.—For purposes of subparagraph (A), administrative remedies under section 503 shall not be deemed exhausted until available remedies under section 803 have been elected and are exhausted by issuance of a final determination by an external appeal entity under such section.

1           “(C) CONSIDERATION OF ADMINISTRATIVE DETERMINA-  
2           TIONS.—Any determinations made under section 802 or 803 made  
3           while an action under this paragraph is pending shall be given due  
4           consideration by the court in such action.

5           “(8) USE OF EXTERNAL APPEAL ENTITY IN ESTABLISHING AB-  
6           SENCE OF SUBSTANTIAL HARM OR CAUSATION IN LITIGATION.—

7           “(A) IN GENERAL.—In any action under this subsection by  
8           an individual in which damages are sought on the basis of sub-  
9           stantial harm to the individual, the defendant may obtain (at its  
10          own expense), under procedures similar to procedures applicable  
11          under section 803, a determination by a qualified external appeal  
12          entity (as defined in section 803(c)(1)) that has not been involved  
13          in any stage of the grievance or appeals process which resulted in  
14          such action as to—

15               “(i) whether such substantial harm has been sustained,  
16               and

17               “(ii) whether the proximate cause of such injury was the  
18               result of the failure of the defendant to exercise ordinary  
19               care, as described in paragraph (1)(A).

20          “(B) EFFECT OF FINDING IN FAVOR OF DEFENDANT.—If the  
21          external appeal entity determines that such an injury has not been  
22          sustained or was not proximately caused by such a failure, such  
23          a finding shall be an affirmative defense, and the action shall be  
24          dismissed forthwith unless such finding is overcome upon a show-  
25          ing of clear and convincing evidence to the contrary. Notwith-  
26          standing subsection (g), in any case in which the plaintiff fails in  
27          any attempt to make such a showing to the contrary, the court  
28          shall award to the defendant reasonable attorney’s fees and the  
29          costs of the action incurred in connection with such failed showing.

30          “(9) REBUTTABLE PRESUMPTION.—In the case of any action com-  
31          menced pursuant to paragraph (1), there shall be a rebuttable pre-  
32          sumption in favor of the decision of the external appeal entity rendered  
33          upon completion of any review elected under section 803 and such pre-  
34          sumption may be overcome only upon a showing of clear and convincing  
35          evidence to the contrary.

36          “(10) MAXIMUM NONECONOMIC DAMAGES.—Total liability for  
37          noneconomic loss under this subsection in connection with any failure  
38          with respect to any participant or beneficiary may not exceed the lesser  
39          of—

40               “(A) \$500,000, or

41               “(B) 2 times the amount of economic loss.

1 The dollar amount under subparagraph (A), shall be increased or de-  
2 creased, for each calendar year that ends after December 31, 2001, by  
3 the same percentage as the percentage by which the medical care ex-  
4 penditure category of the Consumer Price Index for All Urban Con-  
5 sumers (United States city average), published by the Bureau of Labor  
6 Statistics, for September of the preceding calendar year has increased  
7 or decreased from such index for September 2000

8 “(11) PROHIBITION OF AWARD OF PUNITIVE DAMAGES.—

9 “(A) GENERAL RULE.—Except as provided in this paragraph,  
10 nothing in this subsection shall be construed as authorizing a  
11 cause of action for punitive, exemplary, or similar damages.

12 “(B) EXCEPTION.—Punitive damages are authorized in any  
13 case described in paragraph (1)(A)(ii)(II) in which the plaintiff es-  
14 tablishes by clear and convincing evidence that conduct carried out  
15 by the defendant with a conscious, flagrant indifference to the  
16 rights or safety of others was the proximate cause of the harm  
17 that is the subject of the action and that such conduct was con-  
18 trary to the recommendations of an external appeal entity issued  
19 in the determination in such case rendered pursuant to section  
20 803.

21 “(C) LIMITATION ON AMOUNT.—

22 “(i) IN GENERAL.—The amount of punitive damages  
23 that may be awarded in an action described in subparagraph  
24 (B) may not exceed the greater of—

25 “(I) 2 times the sum of the amount awarded to the  
26 claimant for economic loss; or

27 “(II) \$250,000.

28 “(ii) SPECIAL RULE.—Notwithstanding clause (i), in any  
29 action described in subparagraph (B) against an individual  
30 whose net worth does not exceed \$500,000 or against an  
31 owner of an unincorporated business, or any partnership, cor-  
32 poration, association, unit of local government, or organiza-  
33 tion which has fewer than 25 employees, the punitive damages  
34 shall not exceed the lesser of—

35 “(I) 2 times the amount awarded to the claimant  
36 for economic loss; or

37 “(II) \$250,000.

38 “(iii) CONTROLLED GROUPS.—

39 “(I) IN GENERAL.—For the purpose of determining  
40 the applicability of clause (ii) to any employer, in deter-  
41 mining the number of employees of an employer who is



1 a member of a controlled group, the employees of any  
2 person in such group shall be deemed to be employees  
3 of the employer.

4 “(II) CONTROLLED GROUP.—For purposes of sub-  
5 clause (I), the term ‘controlled group’ means any group  
6 treated as a single employer under subsection (b), (c),  
7 (m), or (o) of section 414 of the Internal Revenue Code  
8 of 1986.

9 “(D) EXCEPTION FOR INSUFFICIENT AWARD IN CASES OF  
10 EGREGIOUS CONDUCT.—

11 “(i) DETERMINATION BY COURT.—If the court makes a  
12 determination, based on clear and convincing evidence and  
13 after considering each of the factors in subparagraph (E),  
14 that the application of subparagraph (C) would result in an  
15 award of punitive damages that is insufficient to punish the  
16 egregious conduct of the defendant against whom the punitive  
17 damages are to be awarded or to deter such conduct in the  
18 future, the court shall determine the additional amount of pu-  
19 nitive damages (referred to in this subparagraph as the ‘addi-  
20 tional amount’) in excess of the amount determined in accord-  
21 ance with subparagraph (C) to be awarded against the de-  
22 fendant in a separate proceeding in accordance with this sub-  
23 paragraph.

24 “(ii) ABSOLUTE LIMIT ON PUNITIVES.—Nothing in this  
25 subtitle shall be construed to authorize the court to award an  
26 additional amount greater than an amount equal to the max-  
27 imum amount applicable under subparagraph (C).

28 “(iii) REQUIREMENTS FOR AWARDED ADDITIONAL  
29 AMOUNT.—If the court awards an additional amount pursu-  
30 ant to this subparagraph, the court shall state its reasons for  
31 setting the amount of the additional amount in findings of  
32 fact and conclusions of law.

33 “(E) FACTORS FOR CONSIDERATION IN CASES OF EGREGIOUS  
34 CONDUCT.—In any proceeding under subparagraph (D), the mat-  
35 ters to be considered by the court shall include (but are not lim-  
36 ited to)—

37 “(i) the extent to which the defendant acted with actual  
38 malice;

39 “(ii) the likelihood that serious harm would arise from  
40 the conduct of the defendant;

1 “(iii) the degree of the awareness of the defendant of  
2 that likelihood;

3 “(iv) the profitability of the misconduct to the defendant;

4 “(v) the duration of the misconduct and any concurrent  
5 or subsequent concealment of the conduct by the defendant;

6 “(vi) the attitude and conduct of the defendant upon the  
7 discovery of the misconduct and whether the misconduct has  
8 terminated;

9 “(vii) the financial condition of the defendant; and

10 “(viii) the cumulative deterrent effect of other losses,  
11 damages, and punishment suffered by the defendant as a re-  
12 sult of the misconduct, reducing the amount of punitive dam-  
13 ages on the basis of the economic impact and severity of all  
14 measures to which the defendant has been or may be sub-  
15 jected, including—

16 “(I) compensatory and punitive damage awards to  
17 similarly situated claimants;

18 “(II) the adverse economic effect of stigma or loss  
19 of reputation;

20 “(III) civil fines and criminal and administrative  
21 penalties; and

22 “(IV) stop sale, cease and desist, and other remedial  
23 or enforcement orders.

24 “(F) APPLICATION BY COURT.—This paragraph shall be ap-  
25 plied by the court and, in the case of a trial by jury, application  
26 of this paragraph shall not be disclosed to the jury.

27 “(G) LIMITATION ON PUNITIVE DAMAGES.—No person shall  
28 be liable for punitive, exemplary, or similar damages in an action  
29 under this subsection based on any failure described in paragraph  
30 (1) if such failure was in compliance with the recommendations of  
31 an external appeal entity issued in a determination under section  
32 803.

33 “(H) BIFURCATION AT REQUEST OF ANY PARTY.—

34 “(i) IN GENERAL.—At the request of any party the trier  
35 of fact in any action that is subject to this paragraph shall  
36 consider in a separate proceeding, held subsequent to the de-  
37 termination of the amount of compensatory damages, whether  
38 punitive damages are to be awarded for the harm that is the  
39 subject of the action and the amount of the award.

40 “(ii) INADMISSIBILITY OF EVIDENCE RELATIVE ONLY TO  
41 A CLAIM OF PUNITIVE DAMAGES IN A PROCEEDING CON-

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1 CERNING COMPENSATORY DAMAGES.—If any party requests a  
2 separate proceeding under clause (i), in a proceeding to deter-  
3 mine whether the claimant may be awarded compensatory  
4 damages, any evidence, argument, or contention that is rel-  
5 evant only to the claim of punitive damages, as determined  
6 by applicable State law, shall be inadmissible.

7 “(12) LIMITATION OF ACTION.—Paragraph (1) shall not apply in  
8 connection with any action commenced after the later of—

9 “(A) 1 year after (i) the date of the last action which con-  
10 stituted a part of the failure, or (ii) in the case of an omission,  
11 the latest date on which the fiduciary could have cured the failure,  
12 or

13 “(B) 1 year after the earliest date on which the plaintiff first  
14 knew, or reasonably should have known, of the substantial harm  
15 resulting from the failure.

16 “(13) COORDINATION WITH FIDUCIARY REQUIREMENTS.—A fidu-  
17 ciary shall not be treated as failing to meet any requirement of part  
18 4 solely by reason of any action taken by a fiduciary which consists  
19 of full compliance with the reversal under section 803 of a denial of  
20 claim for benefits (within the meaning of section 801(f)).

21 “(14) CONSTRUCTION.—Nothing in this subsection shall be con-  
22 strued as authorizing a cause of action for the failure to provide an  
23 item or service which is not covered under the group health plan in-  
24 volved.

25 “(15) PROTECTION OF MEDICAL MALPRACTICE AND SIMILAR AC-  
26 TIONS UNDER STATE LAW.—This subsection shall not be construed to  
27 preclude any action under State law (as defined in section 514(c)(1))  
28 not otherwise preempted under this title with respect to the duty (if  
29 any) under such State law imposed on any person to exercise a speci-  
30 fied standard of care when making a health care treatment decision in  
31 any case in which medical services are provided by such person or in  
32 any case in which such decision affects the quality of care or treatment  
33 provided or received.

34 “(16) COEXISTING ACTIONS IN FEDERAL AND STATE COURTS DIS-  
35 ALLOWED.—

36 “(A) PRECEDENCE OF FEDERAL ACTION.—An action may be  
37 commenced under this subsection only if no action for damages  
38 has been commenced by the plaintiff under State law (as defined  
39 in section 514(c)(1)) based on the same substantial harm.

40 “(B) ACTIONS UNDER STATE LAW SUPERSEDED.—Upon the  
41 commencement of any action under this subsection, this subsection

1           supersedes any action authorized under State law (as so defined)  
2           against any person based on the same substantial harm during the  
3           pendency of the action commenced under this subsection.

4           “(C) DOUBLE RECOVERY OF DAMAGES PRECLUDED.—This  
5           subsection supersedes any action under State law (as so defined)  
6           for damages based on any substantial harm to the extent that  
7           damages for such substantial harm have been recovered in an ac-  
8           tion under this subsection.

9           “(17) LIMITATION ON RELIEF WHERE DEFENDANT’S POSITION  
10          PREVIOUSLY SUPPORTED UPON EXTERNAL REVIEW.—In any case in  
11          which the court finds the defendant to be liable in an action under this  
12          subsection, to the extent that such liability is based on a finding by  
13          the court of a particular failure described in paragraph (1) and such  
14          finding is contrary to a determination by an external review entity in  
15          a decision previously rendered under section 803 with respect to such  
16          defendant, no relief shall be available under this subsection in addition  
17          to the relief otherwise available under subsection (a)(1)(B).”.

18          (b) CONFORMING AMENDMENT.—Section 502(a)(1)(A) of such Act (29  
19          U.S.C. 1132(a)(1)(A)) is amended by inserting “or (n)” after “subsection  
20          (c)”.

21          (c) EFFECTIVE DATE.—The amendments made by this section shall  
22          apply to acts and omissions (from which a cause of action arises) occurring  
23          on or after the date of the enactment of this Act.

24          **SEC. 204. AVAILABILITY OF BINDING ARBITRATION.**

25          (a) IN GENERAL.—Section 503 of the Employee Retirement Income  
26          Security Act of 1974 (as amended by the preceding provisions of this Act)  
27          is amended further—

28                 (1) in subsection (a), by inserting “IN GENERAL.—” after “(a)”;

29                 (2) in subsection (b), by striking “(b) In the case” and inserting  
30          the following:

31          “(b) GROUP HEALTH PLANS.—

32                 “(1) IN GENERAL.—In the case”; and

33                 (3) by adding at the end of subsection (b) the following:

34                 “(2) BINDING ARBITRATION PERMITTED AS ALTERNATIVE MEANS  
35          OF DISPUTE RESOLUTION.—

36                 “(A) IN GENERAL.—A group health plan shall not be treated  
37          as failing to meet the requirements of the preceding provisions of  
38          this section relating to review of any adverse coverage decision  
39          rendered by or under the plan, if—

40                         “(i) in lieu of the procedures otherwise provided under  
41                         the plan in accordance with such provisions and in lieu of any

subsequent review of the matter by a court under section 502—

“(I) the aggrieved participant or beneficiary elects in the request for the review a procedure by which the dispute is resolved by binding arbitration which is available under the plan with respect to similarly situated participants and beneficiaries and which meets the requirements of subparagraph (B); or

“(II) in the case of any such plan or portion thereof which is established and maintained pursuant to a bona fide collective bargaining agreement, the plan provides for a procedure by which such disputes are resolved by means of binding arbitration which meets the requirements of subparagraph (B); and

“(ii) the additional requirements of subparagraph (B) are met.

“(B) ADDITIONAL REQUIREMENTS.—The Secretary shall prescribe by regulation requirements for arbitration procedures under this paragraph, including at least the following requirements:

“(i) ARBITRATION PANEL.—The arbitration shall be conducted by an arbitration panel meeting the requirements of subparagraph (C).

“(ii) FAIR PROCESS; DE NOVO DETERMINATION.—The procedure shall provide for a fair, de novo determination.

“(iii) OPPORTUNITY TO SUBMIT EVIDENCE, HAVE REPRESENTATION, AND MAKE ORAL PRESENTATION.—Each party to the arbitration procedure—

“(I) may submit and review evidence related to the issues in dispute;

“(II) may use the assistance or representation of one or more individuals (any of whom may be an attorney); and

“(III) may make an oral presentation.

“(iv) PROVISION OF INFORMATION.—The plan shall provide timely access to all its records relating to the matters under arbitration and to all provisions of the plan relating to such matters.

“(v) TIMELY DECISIONS.—A determination by the arbitration panel on the decision shall—

“(I) be made in writing;

“(II) be binding on the parties; and

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1 “(III) be made in accordance with the medical ex-  
2 igencies of the case involved.

3 “(vi) EXHAUSTION OF EXTERNAL REVIEW REQUIRED.—  
4 The arbitration procedures under this paragraph shall not be  
5 available to party unless the party has exhausted external re-  
6 view procedures under section 804.

7 “(vii) VOLUNTARY ELECTION.—A group health plan may  
8 not require, through the plan document, a contract, or other-  
9 wise, that a participant or beneficiary make the election de-  
10 scribed in subparagraph (A)(i)(I).

11 “(C) ARBITRATION PANEL.—

12 “(i) IN GENERAL.—Arbitrations commenced pursuant to  
13 this paragraph shall be conducted by a panel of arbitrators  
14 selected by the parties made up of 3 individuals, including at  
15 least one practicing physician and one practicing attorney.

16 “(ii) QUALIFICATIONS.—Any individual who is a member  
17 of an arbitration panel shall meet the following requirements:

18 “(I) There is no real or apparent conflict of interest  
19 that would impede the individual conducting arbitration  
20 independent of the plan and meets the independence re-  
21 quirements of clause (iii).

22 “(II) The individual has sufficient medical or legal  
23 expertise to conduct the arbitration for the plan on a  
24 timely basis.

25 “(III) The individual has appropriate credentials  
26 and has attained recognized expertise in the applicable  
27 medical or legal field.

28 “(IV) The individual was not involved in the initial  
29 adverse coverage decision or any other review thereof.

30 “(iii) INDEPENDENCE REQUIREMENTS.—An individual  
31 described in clause (ii) meets the independence requirements  
32 of this clause if—

33 “(I) the individual is not affiliated with any related  
34 party,

35 “(II) any compensation received by such individual  
36 in connection with the binding arbitration procedure is  
37 reasonable and not contingent on any decision rendered  
38 by the individual,

39 “(III) under the terms of the plan, the plan has no  
40 recourse against the individual or entity in connection  
41 with the binding arbitration procedure, and

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1 “(IV) the individual does not otherwise have a con-  
2 flict of interest with a related party as determined under  
3 such regulations as the Secretary may prescribe.

4 “(iv) RELATED PARTY.—For purposes of clause (iii), the  
5 term ‘related party’ means—

6 “(I) the plan or any health insurance issuer offering  
7 health insurance coverage in connection with the plan (or  
8 any officer, director, or management employee of such  
9 plan or issuer),

10 “(II) the physician or other medical care provider  
11 that provided the medical care involved in the coverage  
12 decision,

13 “(III) the institution at which the medical care in-  
14 volved in the coverage decision is provided,

15 “(IV) the manufacturer of any drug or other item  
16 that was included in the medical care involved in the cov-  
17 erage decision, or

18 “(V) any other party determined under such regula-  
19 tions as the Secretary may prescribe to have a substan-  
20 tial interest in the coverage decision .

21 “(iv) AFFILIATED.—For purposes of clause (iii), the  
22 term ‘affiliated’ means, in connection with any entity, having  
23 a familial, financial, or professional relationship with, or in-  
24 terest in, such entity.

25 “(D) DECISIONS.—

26 “(i) IN GENERAL.—Decisions rendered by the arbitration  
27 panel shall be binding on all parties to the arbitration and  
28 shall be enforceable under section 502 as if the terms of the  
29 decision were the terms of the plan, except that the court may  
30 vacate any award made pursuant to the arbitration for any  
31 cause described in paragraph (1), (2), (3), (4), or (5) of sec-  
32 tion 10(a) of title 9, United States Code.

33 “(ii) ALLOWABLE REMEDIES.—The remedies which may  
34 be implemented by the arbitration panel shall consist of those  
35 remedies which would be available in an action timely com-  
36 menced by a participant or beneficiary under section 502  
37 after exhaustion of administrative remedies, except that a  
38 money award may be made in the arbitration proceedings in  
39 any amount not to exceed 3 times the maximum amount of  
40 damages that would be allowable in such case in an action de-  
41 scribed in section 502(n).”.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to adverse coverage decisions initially rendered by group health plans on or after the date of the enactment of this Act.

### **TITLE III— AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986**

#### **SEC. 301. APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986.**

Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

“Sec. 9813. Standard relating to chapter 101.”; and

(2) by inserting after section 9812 the following:

#### **“SEC. 9813. STANDARD RELATING TO CHAPTER 101.**

“A group health plan shall comply with the requirements of chapter 101 and such requirements shall be deemed to be incorporated into this section.”.

#### **SEC. 302. IMPROVING MANAGED CARE.**

(a) IN GENERAL.—The Internal Revenue Code of 1986 is amended by adding at the end the following new chapter:

#### **“CHAPTER 101—IMPROVING MANAGED CARE**

“Subchapter A. Access to care.

“Subchapter B. Access to information.

“Subchapter C. Protecting the doctor-patient relationship.

“Subchapter D. Definitions.

#### **“Subchapter A—Access to Care**

“Sec. 9901. Choice of health care professional.

“Sec. 9902. Access to emergency care.

“Sec. 9903. Access to specialty care.

“Sec. 9904. Access to obstetrical and gynecological care.

“Sec. 9905. Access to pediatric care.

“Sec. 9906. Continuity of care.

“Sec. 9907. Network adequacy.

“Sec. 9908. Access to experimental or investigational prescription drugs.

“Sec. 9909. Coverage for individuals participating in approved cancer clinical trials.

#### **“SEC. 9901. CHOICE OF HEALTH CARE PROFESSIONAL.**

“(a) PRIMARY CARE.—If a group health plan requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan shall permit each participant and beneficiary to designate any participating primary care provider who is available to accept such individual.

“(b) SPECIALISTS.—A group health plan shall permit each participant or beneficiary to receive medically necessary or appropriate specialty care, pursuant to appropriate referral procedures, from any qualified partici-



1     participating health care professional who is available to accept such individual for  
2     such care.

3     **“SEC. 9902. ACCESS TO EMERGENCY CARE.**

4         “(a) COVERAGE OF EMERGENCY SERVICES.—

5             “(1) IN GENERAL.—If a group health plan provides or covers any  
6             benefits with respect to services in an emergency department of a hos-  
7             pital, the plan shall cover emergency services (as defined in paragraph  
8             (2)(B))—

9                 “(A) without the need for any prior authorization determina-  
10                tion;

11               “(B) whether the health care provider furnishing such serv-  
12               ices is a participating provider with respect to such services;

13               “(C) in a manner so that, if such services are provided to a  
14               participant or beneficiary—

15                     “(i) by a nonparticipating health care provider with or  
16                     without prior authorization, or

17                     “(ii) by a participating health care provider without prior  
18                     authorization,

19             the participant or beneficiary is not liable for amounts that exceed  
20             the amounts of liability that would be incurred if the services were  
21             provided by a participating health care provider with prior author-  
22             ization; and

23               “(D) without regard to any other term or condition of such  
24               coverage (other than exclusion or coordination of benefits, or an  
25               affiliation or waiting period, permitted under section 2701 of the  
26               Public Health Service Act, section 701 of the Employee Retire-  
27               ment Income Security Act of 1974, or section 9801 of the Internal  
28               Revenue Code of 1986, and other than applicable cost-sharing).

29         “(2) DEFINITIONS.—In this section:

30             “(A) EMERGENCY MEDICAL CONDITION.—The term ‘emer-  
31             gency medical condition’ means—

32                 “(i) a medical condition manifesting itself by acute  
33                 symptoms of sufficient severity (including severe pain) such  
34                 that a prudent layperson, who possesses an average knowl-  
35                 edge of health and medicine, could reasonably expect the ab-  
36                 sence of immediate medical attention to result in a condition  
37                 described in clause (i), (ii), or (iii) of section 1867(e)(1)(A)  
38                 of the Social Security Act; and

39                 “(ii) a medical condition manifesting itself in a neonate  
40                 by acute symptoms of sufficient severity (including severe  
41                 pain) such that a prudent health care professional could rea-

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sonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

“(B) EMERGENCY SERVICES.—The term ‘emergency services’ means—

“(i) with respect to an emergency medical condition described in subparagraph (A)(i)—

“(I) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

“(II) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient; or

“(ii) with respect to an emergency medical condition described in subparagraph (A)(ii), medical treatment for such condition rendered by a health care provider in a hospital to a neonate, including available hospital ancillary services in response to an urgent request of a health care professional and to the extent necessary to stabilize the neonate.

“(C) STABILIZE.—The term ‘to stabilize’ means, with respect to an emergency medical condition, to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility.

“(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.—If benefits are available under a group health plan with respect to maintenance care or post-stabilization care covered under the guidelines established under section 1852(d)(2) of the Social Security Act, the plan shall provide for reimbursement with respect to such services provided to a participant or beneficiary other than through a participating health care provider in a manner consistent with subsection (a)(1)(C) (and shall otherwise comply with such guidelines).

“(c) COVERAGE OF EMERGENCY AMBULANCE SERVICES.—

“(1) IN GENERAL.—If a group health plan provides any benefits with respect to ambulance services and emergency services, the plan shall cover emergency ambulance services (as defined in paragraph

(2))) furnished under the plan under the same terms and conditions under subparagraphs (A) through (D) of subsection (a)(1) under which coverage is provided for emergency services.

“(2) EMERGENCY AMBULANCE SERVICES.—For purposes of this subsection, the term ‘emergency ambulance services’ means ambulance services (as defined for purposes of section 1861(s)(7) of the Social Security Act) furnished to transport an individual who has an emergency medical condition (as defined in subsection (a)(2)(A)) to a hospital for the receipt of emergency services (as defined in subsection (a)(2)(B)) in a case in which the emergency services are covered under the plan pursuant to subsection (a)(1) and a prudent layperson, with an average knowledge of health and medicine, could reasonably expect that the absence of such transport would result in placing the health of the individual in serious jeopardy, serious impairment of bodily function, or serious dysfunction of any bodily organ or part.

**“SEC. 9903. ACCESS TO SPECIALTY CARE.**

“(a) SPECIALTY CARE FOR COVERED SERVICES.—

“(1) IN GENERAL.—If—

“(A) an individual is a participant or beneficiary under a group health plan,

“(B) the individual has a condition or disease of sufficient seriousness and complexity to require treatment by a specialist or the individual requires physician pathology services, and

“(C) benefits for such treatment or services are provided under the plan,

the plan shall make or provide for a referral to a specialist who is available and accessible (consistent with standards developed under section 9907) to provide the treatment for such condition or disease or to provide such services.

“(2) SPECIALIST DEFINED.—For purposes of this subsection, the term ‘specialist’ means, with respect to a condition or services, a health care practitioner, facility, or center or physician pathologist that has adequate expertise through appropriate training and experience (including, in the case of a child, appropriate pediatric expertise and in the case of a pregnant woman, appropriate obstetrical expertise) to provide high quality care in treating the condition or to provide physician pathology services.

“(3) CARE UNDER REFERRAL.—A group health plan may require that the care provided to an individual pursuant to such referral under paragraph (1) with respect to treatment be—

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1 “(A) pursuant to a treatment plan, only if the treatment plan  
2 is developed by the specialist and approved by the plan, in con-  
3 sultation with the designated primary care provider or specialist  
4 and the individual (or the individual’s designee), and

5 “(B) in accordance with applicable quality assurance and uti-  
6 lization review standards of the plan.

7 Nothing in this subsection shall be construed as preventing such a  
8 treatment plan for an individual from requiring a specialist to provide  
9 the primary care provider with regular updates on the specialty care  
10 provided, as well as all necessary medical information.

11 “(4) REFERRALS TO PARTICIPATING PROVIDERS.—A group health  
12 plan is not required under paragraph (1) to provide for a referral to  
13 a specialist that is not a participating provider, unless the plan does  
14 not have a specialist that is available and accessible to treat the indi-  
15 vidual’s condition or provide physician pathology services and that is  
16 a participating provider with respect to such treatment or services.

17 “(5) REFERRALS TO NONPARTICIPATING PROVIDERS.—In a case  
18 in which a referral of an individual to a nonparticipating specialist is  
19 required under paragraph (1), the group health plan shall provide the  
20 individual the option of at least three nonparticipating specialists.

21 “(6) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan  
22 refers an individual to a nonparticipating specialist pursuant to para-  
23 graph (1), services provided pursuant to the approved treatment plan  
24 (if any) shall be provided at no additional cost to the individual beyond  
25 what the individual would otherwise pay for services received by such  
26 a specialist that is a participating provider.

27 “(b) SPECIALISTS AS GATEKEEPER FOR TREATMENT OF ONGOING  
28 SPECIAL CONDITIONS.—

29 “(1) IN GENERAL.—A group health plan shall have a procedure  
30 by which an individual who is a participant or beneficiary and who has  
31 an ongoing special condition (as defined in paragraph (3)) may request  
32 and receive a referral to a specialist for such condition who shall be  
33 responsible for and capable of providing and coordinating the individ-  
34 ual’s care with respect to the condition. Under such procedures if such  
35 an individual’s care would most appropriately be coordinated by such  
36 a specialist, such plan shall refer the individual to such specialist.

37 “(2) TREATMENT FOR RELATED REFERRALS.—Such specialists  
38 shall be permitted to treat the individual without a referral from the  
39 individual’s primary care provider and may authorize such referrals,  
40 procedures, tests, and other medical services as the individual’s primary  
41 care provider would otherwise be permitted to provide or authorize,

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1 subject to the terms of the treatment (referred to in subsection  
2 (a)(3)(A)) with respect to the ongoing special condition.

3 “(3) ONGOING SPECIAL CONDITION DEFINED.—In this subsection,  
4 the term ‘ongoing special condition’ means a condition or disease  
5 that—

6 “(A) is life-threatening, degenerative, or disabling, and

7 “(B) requires specialized medical care over a prolonged period  
8 of time.

9 “(4) TERMS OF REFERRAL.—The provisions of paragraphs (3)  
10 through (5) of subsection (a) apply with respect to referrals under  
11 paragraph (1) of this subsection in the same manner as they apply to  
12 referrals under subsection (a)(1).

13 “(5) CONSTRUCTION.—Nothing in this subsection shall be con-  
14 strued as preventing an individual who is a participant or beneficiary  
15 and who has an ongoing special condition from having the individual’s  
16 primary care physician assume the responsibilities for providing and co-  
17 ordinating care described in paragraph (1).

18 “(c) STANDING REFERRALS.—

19 “(1) IN GENERAL.—A group health plan shall have a procedure  
20 by which an individual who is a participant or beneficiary and who has  
21 a condition that requires ongoing care from a specialist may receive a  
22 standing referral to such specialist for treatment of such condition. If  
23 the plan, or if the primary care provider in consultation with the med-  
24 ical director of the plan and the specialist (if any), determines that  
25 such a standing referral is appropriate, the plan shall make such a re-  
26 ferral to such a specialist if the individual so desires.

27 “(2) TERMS OF REFERRAL.—The provisions of paragraphs (3)  
28 through (5) of subsection (a) apply with respect to referrals under  
29 paragraph (1) of this subsection in the same manner as they apply to  
30 referrals under subsection (a)(1).

31 **“SEC. 9904. ACCESS TO OBSTETRICAL AND GYNECOLOGICAL CARE.**

32 “(a) IN GENERAL.—If a group health plan requires or provides for a  
33 participant or beneficiary to designate a participating primary care health  
34 care professional, the plan—

35 “(1) may not require authorization or a referral by the individual’s  
36 primary care health care professional or otherwise for covered gynec-  
37 ological care (including preventive women’s health examinations) or for  
38 covered pregnancy-related services provided by a participating physician  
39 (including a family practice physician) who specializes or is trained and  
40 experienced in gynecology or obstetrics, respectively, to the extent such  
41 care is otherwise covered; and

1           “(2) shall treat the ordering of other gynecological or obstetrical  
2           care by such a participating physician as the authorization of the pri-  
3           mary care health care professional with respect to such care under the  
4           plan.

5           “(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed  
6           to—

7           “(1) waive any exclusions of coverage under the terms of the plan  
8           with respect to coverage of gynecological or obstetrical care;

9           “(2) preclude the group health plan involved from requiring that  
10          the gynecologist or obstetrician notify the primary care health care pro-  
11          fessional or the plan of treatment decisions; or

12          “(3) prevent a plan from offering, in addition to physicians de-  
13          scribed in subsection (a)(1), non-physician health care professionals  
14          who are trained and experienced in gynecology or obstetrics.

15       **“SEC. 9905. ACCESS TO PEDIATRIC CARE.**

16          “(a) PEDIATRIC CARE.—If a group health plan requires or provides for  
17          a participant or beneficiary to designate a participating primary care pro-  
18          vider for a child of such individual, the plan shall permit the individual to  
19          designate a physician (including a family practice physician) who specializes  
20          or is trained and experienced in pediatrics as the child’s primary care pro-  
21          vider.

22          “(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed to  
23          waive any exclusions of coverage under the terms of the plan with respect  
24          to coverage of pediatric care.

25       **“SEC. 9906. CONTINUITY OF CARE.**

26          “(a) IN GENERAL.—

27               “(1) TERMINATION OF PROVIDER.—If a contract between a group  
28               health plan and a health care provider is terminated (as defined in  
29               paragraph (3)(B)), or benefits or coverage provided by a health care  
30               provider are terminated because of a change in the terms of provider  
31               participation in a group health plan, and an individual who is a partici-  
32               pant or beneficiary in the plan is undergoing treatment from the pro-  
33               vider for an ongoing special condition (as defined in paragraph (3)(A))  
34               at the time of such termination, the plan shall—

35                       “(A) notify the individual on a timely basis of such termi-  
36                       nation and of the right to elect continuation of coverage of treat-  
37                       ment by the provider under this section; and

38                       “(B) subject to subsection (c), permit the individual to elect  
39                       to continue to be covered with respect to treatment by the provider  
40                       of such condition during a transitional period (provided under sub-  
41                       section (b)).

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1           “(2) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH  
2           INSURANCE ISSUER.—If a contract for the provision of health insur-  
3           ance coverage between a group health plan and a health insurance  
4           issuer is terminated and, as a result of such termination, coverage of  
5           services of a health care provider is terminated with respect to an indi-  
6           vidual, the provisions of paragraph (1) (and the succeeding provisions  
7           of this section) shall apply under the plan in the same manner as if  
8           there had been a contract between the plan and the provider that had  
9           been terminated, but only with respect to benefits that are covered  
10          under the plan after the contract termination.

11          “(3) DEFINITIONS.—For purposes of this section:

12           “(A) ONGOING SPECIAL CONDITION.—The term ‘ongoing spe-  
13           cial condition’ has the meaning given such term in section  
14           9903(b)(3), and also includes pregnancy.

15           “(B) TERMINATION.—The term ‘terminated’ includes, with  
16           respect to a contract, the expiration or nonrenewal of the contract,  
17           but does not include a termination of the contract by the plan for  
18           failure to meet applicable quality standards or for fraud.

19          “(b) TRANSITIONAL PERIOD.—

20           “(1) IN GENERAL.—Except as provided in paragraphs (2) through  
21           (4), the transitional period under this subsection shall extend up to 90  
22           days (as determined by the treating health care professional) after the  
23           date of the notice described in subsection (a)(1)(A) of the provider’s  
24           termination.

25           “(2) SCHEDULED SURGERY AND ORGAN TRANSPLANTATION.—If  
26           surgery or organ transplantation was scheduled for an individual before  
27           the date of the announcement of the termination of the provider status  
28           under subsection (a)(1)(A) or if the individual on such date was on an  
29           established waiting list or otherwise scheduled to have such surgery or  
30           transplantation, the transitional period under this subsection with re-  
31           spect to the surgery or transplantation shall extend beyond the period  
32           under paragraph (1) and until the date of discharge of the individual  
33           after completion of the surgery or transplantation.

34          “(3) PREGNANCY.—If—

35           “(A) a participant or beneficiary was determined to be preg-  
36           nant at the time of a provider’s termination of participation, and

37           “(B) the provider was treating the pregnancy before date of  
38           the termination,

39          the transitional period under this subsection with respect to provider’s  
40          treatment of the pregnancy shall extend through the provision of post-  
41          partum care directly related to the delivery.

1 “(4) TERMINAL ILLNESS.—If—

2 “(A) a participant or beneficiary was determined to be termi-  
3 nally ill (as determined under section 1861(dd)(3)(A) of the Social  
4 Security Act) at the time of a provider’s termination of participa-  
5 tion, and

6 “(B) the provider was treating the terminal illness before the  
7 date of termination,

8 the transitional period under this subsection shall extend for the re-  
9 mainder of the individual’s life for care directly related to the treat-  
10 ment of the terminal illness or its medical manifestations.

11 “(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan  
12 may condition coverage of continued treatment by a provider under sub-  
13 section (a)(1)(B) upon the individual notifying the plan of the election of  
14 continued coverage and upon the provider agreeing to the following terms  
15 and conditions:

16 “(1) The provider agrees to accept reimbursement from the plan  
17 and individual involved (with respect to cost-sharing) at the rates appli-  
18 cable prior to the start of the transitional period as payment in full  
19 (or, in the case described in subsection (a)(2), at the rates applicable  
20 under the replacement plan after the date of the termination of the  
21 contract with the health insurance issuer) and not to impose cost-shar-  
22 ing with respect to the individual in an amount that would exceed the  
23 cost-sharing that could have been imposed if the contract referred to  
24 in subsection (a)(1) had not been terminated.

25 “(2) The provider agrees to adhere to the quality assurance stand-  
26 ards of the plan responsible for payment under paragraph (1) and to  
27 provide to such plan necessary medical information related to the care  
28 provided.

29 “(3) The provider agrees otherwise to adhere to such plan’s poli-  
30 cies and procedures, including procedures regarding referrals and ob-  
31 taining prior authorization and providing services pursuant to a treat-  
32 ment plan (if any) approved by the plan.

33 “(d) CONSTRUCTION.—Nothing in this section shall be construed to re-  
34 quire the coverage of benefits which would not have been covered if the pro-  
35 vider involved remained a participating provider.

36 **“SEC. 9907. NETWORK ADEQUACY.**

37 “(a) REQUIREMENT.—A group health plan shall meet such standards  
38 for network adequacy as are established by law pursuant to this section.

39 “(b) DEVELOPMENT OF STANDARDS.—



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1           “(1) ESTABLISHMENT OF PANEL.—There is established a panel to  
2 be known as the Health Care Panel to Establish Network Adequacy  
3 Standards (in this section referred to as the ‘Panel’).

4           “(2) DUTIES OF PANEL.—The Panel shall devise standards for  
5 group health plans and to ensure that—

6               “(A) participants and beneficiaries have access to a sufficient  
7 number, mix, and distribution of health care professionals and  
8 providers; and

9               “(B) covered items and services are available and accessible  
10 to each participant and beneficiary—

11                   “(i) in the service area of the plan;

12                   “(ii) at a variety of sites of service;

13                   “(iii) with reasonable promptness (including reasonable  
14 hours of operation and after hours services);

15                   “(iv) with reasonable proximity to the residences or  
16 workplaces of participants and beneficiaries; and

17                   “(v) in a manner that takes into account the diverse  
18 needs of such individuals and reasonably assures continuity of  
19 care.

20           “(c) MEMBERSHIP.—

21               “(1) SIZE AND COMPOSITION.—The Panel shall be composed of 15  
22 members. The Secretary of Health and Human Services, the Majority  
23 Leader of the Senate, and the Speaker of House of Representatives  
24 shall each appoint 1 member from representatives of private insurance  
25 organizations, consumer groups, State insurance commissioners, State  
26 medical societies, and State medical specialty societies.

27               “(2) TERMS OF APPOINTMENT.—The members of the Panel shall  
28 serve for the life of the Panel.

29               “(3) VACANCIES.—A vacancy in the Panel shall not affect the  
30 power of the remaining members to execute the duties of the Panel,  
31 but any such vacancy shall be filled in the same manner in which the  
32 original appointment was made.

33           “(d) PROCEDURES.—

34               “(1) MEETINGS.—The Panel shall meet at the call of a majority  
35 of its members.

36               “(2) FIRST MEETING.—The Panel shall convene not later than 60  
37 days after the date of the enactment of the Health Care Quality and  
38 Choice Act of 1999.

39               “(3) QUORUM.—A quorum shall consist of a majority of the mem-  
40 bers of the Panel.

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1           “(4) HEARINGS.—For the purpose of carrying out its duties, the  
2           Panel may hold such hearings and undertake such other activities as  
3           the Panel determines to be necessary to carry out its duties.

4           “(e) ADMINISTRATION.—

5           “(1) COMPENSATION.—Except as provided in paragraph (1),  
6           members of the Panel shall receive no additional pay, allowances, or  
7           benefits by reason of their service on the Panel.

8           “(2) TRAVEL EXPENSES AND PER DIEM.—Each member of the  
9           Panel who is not an officer or employee of the Federal Government  
10          shall receive travel expenses and per diem in lieu of subsistence in ac-  
11          cordance with sections 5702 and 5703 of title 5, United States Code.

12          “(3) CONTRACT AUTHORITY.—The Panel may contract with and  
13          compensate government and private agencies or persons for items and  
14          services, without regard to section 3709 of the Revised Statutes (41  
15          U.S.C. 5).

16          “(4) USE OF MAILS.—The Panel may use the United States mails  
17          in the same manner and under the same conditions as Federal agencies  
18          and shall, for purposes of the frank, be considered a commission of  
19          Congress as described in section 3215 of title 39, United States Code.

20          “(5) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of  
21          the Panel, the Secretary of Health and Human Services shall provide  
22          to the Panel on a reimbursable basis such administrative support serv-  
23          ices as the Panel may request.

24          “(f) REPORT AND ESTABLISHMENT OF STANDARDS.—Not later than  
25          2 years after the first meeting, the Panel shall submit a report to Congress  
26          and the Secretary of Health and Human Services detailing the standards  
27          devised under subsection (b) and recommendations regarding the implemen-  
28          tation of such standards. Such standards shall take effect to the extent pro-  
29          vided by Federal law enacted after the date of the submission of such re-  
30          port.

31          “(g) TERMINATION.—The Panel shall terminate on the day after sub-  
32          mitting its report to the Secretary of Health and Human Services under  
33          subsection (f).

34          **“SEC. 9908. ACCESS TO EXPERIMENTAL OR INVESTIGATIONAL PRE-**  
35          **SCRIPTION DRUGS.**

36          “No use of a prescription drug or medical device shall be considered  
37          experimental or investigational under a group health plan if such use is in-  
38          cluded in the labeling authorized by the U.S. Food and Drug Administra-  
39          tion under section 505, 513 or 515 of the Federal Food, Drug, and Cos-  
40          metic Act (21 U.S.C. 355) or under section 351 of the Public Health Serv-

1 ice Act (42 U.S.C. 262), unless such use is demonstrated to be unsafe or  
2 ineffective.

3 **“SEC. 9909. COVERAGE FOR INDIVIDUALS PARTICIPATING IN AP-**  
4 **PROVED CANCER CLINICAL TRIALS.**

5 “(a) COVERAGE.—

6 “(1) IN GENERAL.—If a group health plan provides coverage to  
7 a qualified individual (as defined in subsection (b)), the plan—

8 “(A) may not deny the individual participation in the clinical  
9 trial referred to in subsection (b)(2);

10 “(B) subject to subsections (b), (c), and (d), may not deny  
11 (or limit or impose additional conditions on) the coverage of rou-  
12 tine patient costs for items and services furnished in connection  
13 with participation in the trial; and

14 “(C) may not discriminate against the individual on the basis  
15 of the individual’s participation in such trial.

16 “(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph  
17 (1)(B), routine patient costs do not include the cost of the tests or  
18 measurements conducted primarily for the purpose of the clinical trial  
19 involved.

20 “(3) USE OF IN-NETWORK PROVIDERS.—If one or more partici-  
21 pating providers is participating in a clinical trial, nothing in para-  
22 graph (1) shall be construed as preventing a plan from requiring that  
23 a qualified individual participate in the trial through such a partici-  
24 pating provider if the provider will accept the individual as a partici-  
25 pant in the trial.

26 “(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection  
27 (a), the term ‘qualified individual’ means an individual who is a participant  
28 or beneficiary in a group health plan and who meets the following condi-  
29 tions:

30 “(1)(A) The individual has been diagnosed with cancer.

31 “(B) The individual is eligible to participate in an approved clin-  
32 ical trial according to the trial protocol with respect to treatment of  
33 such illness.

34 “(C) The individual’s participation in the trial offers meaningful  
35 potential for significant clinical benefit for the individual.

36 “(2) Either—

37 “(A) the referring physician is a participating health care  
38 professional and has concluded that the individual’s participation  
39 in such trial would be appropriate based upon the individual meet-  
40 ing the conditions described in paragraph (1); or

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1           “(B) the individual provides medical and scientific informa-  
2           tion establishing that the individual’s participation in such trial  
3           would be appropriate based upon the individual meeting the condi-  
4           tions described in paragraph (1).

5           “(c) PAYMENT.—

6           “(1) IN GENERAL.—Under this section a group health plan shall  
7           provide for payment for routine patient costs described in subsection  
8           (a)(2) but is not required to pay for costs of items and services that  
9           are reasonably expected to be paid for by the sponsors of an approved  
10          clinical trial.

11          “(2) ROUTINE PATIENT CARE COSTS.—For purposes of this  
12          section—

13           “(A) IN GENERAL.—The term ‘routine patient care costs’ in-  
14           cludes the costs associated with the provision of items and services  
15           that—

16           “(i) would otherwise be covered under the group health  
17           plan if such items and services were not provided in connec-  
18           tion with an approved clinical trial program; and

19           “(ii) are furnished according to the protocol of an ap-  
20           proved clinical trial program.

21          “(B) EXCLUSION.—Such term does include the costs associ-  
22          ated with the provision of—

23           “(i) an investigational drug or device, unless the Sec-  
24           retary has authorized the manufacturer of such drug or de-  
25           vice to charge for such drug or device; or

26           “(ii) any item or service supplied without charge by the  
27           sponsor of the approved clinical trial program.

28          “(3) PAYMENT RATE.—In the case of covered items and services  
29          provided by—

30           “(A) a participating provider, the payment rate shall be at  
31           the agreed upon rate, or

32           “(B) a nonparticipating provider, the payment rate shall be  
33           at the rate the plan would normally pay for comparable items or  
34           services under subparagraph (A).

35          “(d) APPROVED CLINICAL TRIAL DEFINED.—In this section, the term  
36          ‘approved clinical trial’ means a cancer clinical research study or cancer  
37          clinical investigation approved by an Institutional Review Board.

38          “(e) CONSTRUCTION.—Nothing in this section shall be construed to  
39          limit a plan’s coverage with respect to clinical trials.

40          “(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBIL-  
41          ITIES OF FIDUCIARIES.—

“(1) IN GENERAL.—For purposes of this section, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this section with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

“(2) CONSTRUCTION.—Nothing in this section shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B of the Employee Retirement Income Security Act of 1974.

#### **“Subchapter B—Access to Information**

“Sec. 9911. Patient access to information.

#### **“SEC. 9911. PATIENT ACCESS TO INFORMATION.**

“(a) DISCLOSURE REQUIREMENT.—A group health plan shall—

“(1) provide to participants and beneficiaries at the time of initial coverage under the plan (or the effective date of this section, in the case of individuals who are participants or beneficiaries as of such date), and at least annually thereafter, the information described in subsection (b);

“(2) provide to participants and beneficiaries, within a reasonable period (as specified by the Secretary) before or after the date of significant changes in the information described in subsection (b), information on such significant changes; and

“(3) upon request, make available to participants and beneficiaries, the Secretary, and prospective participants and beneficiaries, the information described in subsection (b) or (c).

The plan may charge a reasonable fee for provision in printed form of any of the information described in subsection (b) or (c) more than once during any plan year.

“(b) INFORMATION PROVIDED.—The information described in this subsection with respect to a group health plan shall be provided to a participant or beneficiary free of charge at least once a year and includes the following:

“(1) SERVICE AREA.—The service area of the plan.

“(2) BENEFITS.—Benefits offered under the plan, including—

“(A) those that are covered benefits “(all of which shall be referred to by such relevant CPT and DRG codes as are available), limits and conditions on such benefits, and those benefits that are explicitly excluded from coverage (all of which shall be referred to by such relevant CPT and DRG codes as are available);

1 “(B) cost sharing, such as deductibles, coinsurance, and co-  
2 payment amounts, including any liability for balance billing, any  
3 maximum limitations on out of pocket expenses, and the maximum  
4 out of pocket costs for services that are provided by nonpartici-  
5 pating providers or that are furnished without meeting the appli-  
6 cable utilization review requirements;

7 “(C) the extent to which benefits may be obtained from non-  
8 participating providers;

9 “(D) the extent to which a participant or beneficiary may se-  
10 lect from among participating providers and the types of providers  
11 participating in the plan network;

12 “(E) process for determining experimental coverage; and

13 “(F) use of a prescription drug formulary.

14 “(3) ACCESS.—A description of the following:

15 “(A) The number, mix, and distribution of providers under  
16 the plan.

17 “(B) Out-of-network coverage (if any) provided by the plan.

18 “(C) Any point-of-service option (including any supplemental  
19 premium or cost-sharing for such option).

20 “(D) The procedures for participants and beneficiaries to se-  
21 lect, access, and change participating primary and specialty pro-  
22 viders.

23 “(E) The rights and procedures for obtaining referrals (in-  
24 cluding standing referrals) to participating and nonparticipating  
25 providers.

26 “(F) The name, address, and telephone number of partici-  
27 pating health care providers and an indication of whether each  
28 such provider is available to accept new patients.

29 “(G) Any limitations imposed on the selection of qualifying  
30 participating health care providers, including any limitations im-  
31 posed under section 9901(b)(2).

32 “(4) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by  
33 the plan.

34 “(5) EMERGENCY COVERAGE.—Coverage of emergency services,  
35 including—

36 “(A) the appropriate use of emergency services, including use  
37 of the 911 telephone system or its local equivalent in emergency  
38 situations and an explanation of what constitutes an emergency  
39 situation;

40 “(B) the process and procedures of the plan for obtaining  
41 emergency services; and

1           “(C) the locations of (i) emergency departments, and (ii)  
2           other settings, in which plan physicians and hospitals provide  
3           emergency services and post-stabilization care.

4           “(6) PRIOR AUTHORIZATION RULES.—Rules regarding prior au-  
5           thorization or other review requirements that could result in noncov-  
6           erage or nonpayment.

7           “(7) GRIEVANCE AND APPEALS PROCEDURES.—All appeal or  
8           grievance rights and procedures under the plan, including the method  
9           for filing grievances and the time frames and circumstances for acting  
10          on grievances and appeals.

11          “(8) ACCOUNTABILITY.—A description of the legal recourse op-  
12          tions available for participants and beneficiaries under the plan  
13          including—

14               “(A) the preemption that applies under section 514 of the  
15               Employee Retirement Income Security Act of 1974 (29 U.S.C.  
16               1144) to certain actions arising out of the provision of health ben-  
17               efits; and

18               “(B) the extent to which coverage decisions made by the plan  
19               are subject to internal review or any external review and the prop-  
20               er time frames under

21          “(9) QUALITY ASSURANCE.—Any information made public by an  
22          accrediting organization in the process of accreditation of the plan or  
23          any additional quality indicators the plan makes available.

24          “(10) INFORMATION ON TREATMENT AUTHORIZATION.—Notice of  
25          appropriate mailing addresses and telephone numbers to be used by  
26          participants and beneficiaries in seeking information or authorization  
27          for treatment.

28          “(11) AVAILABILITY OF INFORMATION ON REQUEST.—Notice that  
29          the information described in subsection (c) is available upon request.

30          “(c) INFORMATION MADE AVAILABLE UPON REQUEST.—The informa-  
31          tion described in this subsection is the following:

32               “(1) UTILIZATION REVIEW ACTIVITIES.—A description of proce-  
33               dures used and requirements (including circumstances, time frames,  
34               and appeal rights) under any utilization review program maintained by  
35               the plan.

36               “(2) GRIEVANCE AND APPEALS INFORMATION.—Information on  
37               the number of grievances and appeals and on the disposition in the ag-  
38               gregate of such matters.

39               “(3) FORMULARY RESTRICTIONS.—A description of the nature of  
40               any drug formula restrictions.





1 “(3) as requiring a plan that offers network coverage to include  
2 for participation every willing provider who meets the terms and condi-  
3 tions of the plan; or

4 “(4) as prohibiting a family practice physician with appropriate  
5 expertise from providing pediatric or obstetrical or gynecological care.

6 **“SEC. 9923. PROHIBITION AGAINST IMPROPER INCENTIVE ARRANGE-**  
7 **MENTS.**

8 “(a) IN GENERAL.—A group health plan may not operate any physi-  
9 cian incentive plan (as defined in subparagraph (B) of section 1876(i)(8)  
10 of the Social Security Act) unless the requirements described in clauses (i),  
11 (ii)(I), and (iii) of subparagraph (A) of such section are met with respect  
12 to such a plan.

13 “(b) APPLICATION.—For purposes of carrying out paragraph (1), any  
14 reference in section 1876(i)(8) of the Social Security Act to the Secretary,  
15 an eligible organization, or an individual enrolled with the organization shall  
16 be treated as a reference to the Secretary of the Treasury, a group health  
17 plan, and a participant or beneficiary with the plan, respectively.

18 “(c) CONSTRUCTION.—Nothing in this section shall be construed as  
19 prohibiting all capitation and similar arrangements or all provider discount  
20 arrangements.

21 **“SEC. 9924. PAYMENT OF CLEAN CLAIMS.**

22 “A group health plan shall provide for prompt payment of claims sub-  
23 mitted for health care services or supplies furnished to a participant or ben-  
24 efiary with respect to benefits covered by the plan, in a manner consistent  
25 with the provisions of sections 1816(c)(2) and 1842(c)(2) of the Social Se-  
26 curity Act (42 U.S.C. 1395h(c)(2) and 42 U.S.C. 1395u(c)(2)), except that  
27 for purposes of this section, subparagraph (C) of section 1816(c)(2) of the  
28 Social Security Act shall be treated as applying to claims received from a  
29 participant or beneficiary as well as claims referred to in such subpara-  
30 graph.

31 **“Subchapter D—Definitions**

“Sec. 9931. Definitions.

“Sec. 9933. Exclusions.

“Sec. 9933. Coverage of limited scope plans.

“Sec. 9934. Regulations; coordination; application under different laws.

32 **“SEC. 9931. DEFINITIONS.**

33 For purposes of this chapter—

34 “(a) INCORPORATION OF GENERAL DEFINITIONS.—Except as other-  
35 wise provided, the provisions of section 9831 shall apply for purposes of this  
36 chapter in the same manner as they apply for purposes of chapter 100.

37 “(b) ADDITIONAL DEFINITIONS.—For purposes of this chapter:

1           “(1) CLINICAL PEER.—The term ‘clinical peer’ means, with re-  
2           spect to a review or appeal, a practicing physician or other health care  
3           professional who holds a nonrestricted license and who is—

4           “(A) appropriately certified by a nationally recognized, peer  
5           reviewed accrediting body in the same or similar specialty as typi-  
6           cally manages the medical condition, procedure, or treatment  
7           under review or appeal, or

8           “(B) is trained and experienced in managing such condition,  
9           procedure, or treatment,

10          and includes a pediatric specialist where appropriate; except that only  
11          a physician may be a clinical peer with respect to the review or appeal  
12          of treatment recommended or rendered by a physician.

13          “(2) HEALTH CARE PROFESSIONAL.—The term ‘health care pro-  
14          fessional’ means an individual who is licensed, accredited, or certified  
15          under State law to provide specified health care services and who is op-  
16          erating within the scope of such licensure, accreditation, or certifi-  
17          cation.

18          “(3) HEALTH CARE PROVIDER.—The term ‘health care provider’  
19          includes a physician or other health care professional, as well as an in-  
20          stitutional or other facility or agency that provides health care services  
21          and that is licensed, accredited, or certified to provide health care items  
22          and services under applicable State law.

23          “(4) NETWORK.—The term ‘network’ means, with respect to a  
24          group health plan, the participating health care professionals and pro-  
25          viders through whom the plan provides health care items and services  
26          to participants or beneficiaries.

27          “(5) NONPARTICIPATING.—The term ‘nonparticipating’ means,  
28          with respect to a health care provider that provides health care items  
29          and services to a participant or beneficiary under group health plan,  
30          a health care provider that is not a participating health care provider  
31          with respect to such items and services.

32          “(6) PARTICIPATING.—The term ‘participating’ means, with re-  
33          spect to a health care provider that provides health care items and  
34          services to a participant or beneficiary under group health plan, a  
35          health care provider that furnishes such items and services under a  
36          contract or other arrangement with the plan.

37          “(7) PHYSICIAN.—The term ‘physician’ means an allopathic or os-  
38          teopathic physician.

39          “(8) PRACTICING PHYSICIAN.—The term ‘practicing physician’  
40          means a physician who is licensed in the State in which the physician

1       furnishes professional services and who provides professional services to  
2       individual patients on average at least two full days per week.

3       “(9) PRIOR AUTHORIZATION.—The term ‘prior authorization’  
4       means the process of obtaining prior approval from a group health plan  
5       for the provision or coverage of medical services.

6       **“SEC. 9932. EXCLUSIONS.**

7       “(a) NO BENEFIT REQUIREMENTS.—Nothing in this chapter shall be  
8       construed to require a group health plan to provide specific benefits under  
9       the terms of such plan, other than those provided under the terms of such  
10      plan.

11      “(b) EXCLUSION FOR FEE-FOR-SERVICE COVERAGE.—

12      “(1) GROUP HEALTH PLANS.—The provisions of sections 9901  
13      through 9911 shall not apply to a group health plan if the only cov-  
14      erage offered under the plan is fee-for-service coverage (as defined in  
15      paragraph (2)).

16      “(2) FEE-FOR-SERVICE COVERAGE DEFINED.—For purposes of  
17      this subsection, the term ‘fee-for-service coverage’ means coverage  
18      under a group health plan that—

19      “(A) reimburses hospitals, health professionals, and other  
20      providers on a fee-for-service basis without placing the provider at  
21      financial risk;

22      “(B) does not vary reimbursement for such a provider based  
23      on an agreement to contract terms and conditions or the utiliza-  
24      tion of health care items or services relating to such provider;

25      “(C) allows access to any provider that is lawfully authorized  
26      to provide the covered services and agree to accept the terms and  
27      conditions of payment established under the plan; and

28      “(D) for which the plan does not require prior authorization  
29      before providing for any health care services.

30      **“SEC. 9933. COVERAGE OF LIMITED SCOPE PLANS.**

31      “Only for purposes of applying the requirements of this chapter under  
32      section 9813, section 9832(c)(2)(A) shall be deemed not to apply.

33      **“SEC. 9934. REGULATIONS.**

34      “The Secretary of the Treasury shall issue such regulations as may be  
35      necessary or appropriate to carry out this chapter under section 9813. The  
36      Secretary may promulgate such regulations in the form of interim final  
37      rules as may be necessary to carry out this chapter in a timely manner.”.

38      (b) CLERICAL AMENDMENT.—The table of chapters for subtitle K of  
39      the Internal Revenue Code of 1986 is amended by adding at the end the  
40      following new item:

“CHAPTER 101. Improving managed care.”

**TITLE IV—EFFECTIVE DATES;  
COORDINATION IN IMPLEMENTATION**

**SEC. 401. EFFECTIVE DATES.**

(a) GROUP HEALTH COVERAGE.—

(1) IN GENERAL.—Subject to paragraph (2), the amendments made by title I (other than section 102), sections 201 and 202, and title III shall apply with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning on or after January 1, 2000 (in this section referred to as the “general effective date”) and also shall apply to portions of plan years occurring on and after such date.

(2) TREATMENT OF COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this Act, the amendments made by title I (other than section 102), sections 201 and 202, and title III shall not apply to plan years beginning before the later of—

(A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of enactment of this Act), or

(B) the general effective date.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this Act shall not be treated as a termination of such collective bargaining agreement.

(b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The amendments made by section 102 shall apply with respect to individual health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after the general effective date.

(c) TREATMENT OF RELIGIOUS NONMEDICAL PROVIDERS.—

(1) IN GENERAL.—Nothing in this Act (or the amendments made thereby) shall be construed to—

(A) restrict or limit the right of group health plans, and of health insurance issuers offering health insurance coverage, to include as providers religious nonmedical providers;

(B) require such plans or issuers to—

(i) utilize medically based eligibility standards or criteria in deciding provider status of religious nonmedical providers;

(ii) use medical professionals or criteria to decide patient access to religious nonmedical providers;

(iii) utilize medical professionals or criteria in making decisions in internal or external appeals regarding coverage for care by religious nonmedical providers; or

(iv) compel a participant or beneficiary to undergo a medical examination or test as a condition of receiving health insurance coverage for treatment by a religious nonmedical provider; or

(C) require such plans or issuers to exclude religious nonmedical providers because they do not provide medical or other required data, if such data is inconsistent with the religious nonmedical treatment or nursing care provided by the provider.

(2) RELIGIOUS NONMEDICAL PROVIDER.—For purposes of this subsection, the term “religious nonmedical provider” means a provider who provides no medical care but who provides only religious nonmedical treatment or religious nonmedical nursing care.

**SEC. 402. COORDINATION IN IMPLEMENTATION.**

The Secretary of Labor, the Secretary of Health and Human Services, and the Secretary of the Treasury shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which both Secretaries have responsibility under the provisions of this Act (and the amendments made thereby) are administered so as to have the same effect at all times; and

(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

**TITLE V—OTHER PROVISIONS**

**Subtitle A—Protection of Information**

**SEC. 501. PROTECTION FOR CERTAIN INFORMATION.**

(a) PROTECTION OF CERTAIN INFORMATION.—Notwithstanding any other provision of Federal or State law, health care response information shall be exempt from any disclosure requirement (regardless of whether the requirement relates to subpoenas, discovery, introduction of evidence, testimony, or any other form of disclosure), in connection with a civil or administrative proceeding under Federal or State law, to the same extent as infor-

1     mation developed by a health care provider with respect to any of the fol-  
2     lowing:

- 3             (1) Peer review.
- 4             (2) Utilization review.
- 5             (3) Quality management or improvement.
- 6             (4) Quality control.
- 7             (5) Risk management.
- 8             (6) Internal review for purposes of reducing mortality, morbidity,  
9             or for improving patient care or safety.

10     (b) NO WAIVER OF PROTECTION THROUGH INTERACTION WITH AC-  
11     CREDITING BODY.—Notwithstanding any other provision of Federal or  
12     State law, the protection of health care response information from disclosure  
13     provided under subsection (a) shall not be deemed to be modified or in any  
14     way waived by—

- 15             (1) the development of such information in connection with a re-  
16             quest or requirement of an accrediting body; or
- 17             (2) the transfer of such information to an accrediting body.

18     (c) DEFINITIONS.—For purposes of this section:

19             (1) ACCREDITING BODY.—The term “accrediting body” means a  
20             national, not-for-profit organization that—

- 21                     (A) accredits health care providers; and
- 22                     (B) is recognized as an accrediting body by statute or by a  
23             Federal or State agency that regulates health care providers.

24             (2) HEALTH CARE RESPONSE INFORMATION.—The term “health  
25     care response information” means information (including any data, re-  
26     port, record, memorandum, analysis, statement, or other communica-  
27     tion) developed by, or on behalf of, a health care provider in response  
28     to a serious, adverse, patient related event—

- 29                     (A) during the course of analyzing or studying the event and  
30             its causes; and
- 31                     (B) for the purposes of—
  - 32                             (i) reducing mortality or morbidity; or
  - 33                             (ii) improving patient care or safety (including the pro-  
34                             vider’s notification to an accrediting body and the provider’s  
35                             plans of action in response to such event).

36             (3) HEALTH CARE PROVIDER.—The term “health care provider”  
37     means a person, who with respect to a specific item of protected health  
38     information, receives, creates, uses, maintains, or discloses the informa-  
39     tion while acting in whole or in part in the capacity of—

- 40                     (A) a person who is licensed, certified, registered, or other-  
41             wise authorized by Federal or State law to provide an item or

1 service that constitutes health care in the ordinary course of busi-  
2 ness, or practice of a profession;

3 (B) a Federal, State, or employer-sponsored or any other pri-  
4 vately-sponsored program that directly provides items or services  
5 that constitute health care to beneficiaries; or

6 (C) an officer or employee of a person described in subpara-  
7 graph (A) or (B).

8 (4) STATE.—The term “State” includes a State, the District of  
9 Columbia, the Northern Mariana Islands, any political subdivisions of  
10 a State or such Islands, or any agency or instrumentality of either.

11 (d) EFFECTIVE DATE.—The provisions of this section are effective on  
12 the date of the enactment of this Act.

### 13 **Subtitle B—Other Matters**

#### 14 **SEC. 511. HEALTH CARE PAPERWORK SIMPLIFICATION.**

15 (a) ESTABLISHMENT OF PANEL.—

16 (1) ESTABLISHMENT.—There is established a panel to be known  
17 as the Health Care Panel to Devise a Uniform Explanation of Benefits  
18 (in this section referred to as the “Panel”).

19 (2) DUTIES OF PANEL.—

20 (A) IN GENERAL.—The Panel shall devise a single form for  
21 use by third-party health care payers for the remittance of claims  
22 to providers.

23 (B) DEFINITION.—For purposes of this section, the term  
24 “third-party health care payer” means any entity that contrac-  
25 tually pays health care bills for an individual.

26 (3) MEMBERSHIP.—

27 (A) SIZE AND COMPOSITION.—The Secretary of Health and  
28 Human Services, in consultation with the Majority Leader of the  
29 Senate and the Speaker of the House of Representatives, shall de-  
30 termine the number of members and the composition of the Panel.  
31 Such Panel shall include equal numbers of representatives of pri-  
32 vate insurance organizations, consumer groups, State insurance  
33 commissioners, State medical societies, State hospital associations,  
34 and State medical specialty societies.

35 (B) TERMS OF APPOINTMENT.—The members of the Panel  
36 shall serve for the life of the Panel.

37 (C) VACANCIES.—A vacancy in the Panel shall not affect the  
38 power of the remaining members to execute the duties of the  
39 Panel, but any such vacancy shall be filled in the same manner  
40 in which the original appointment was made.

41 (4) PROCEDURES.—

## 120

1 (A) MEETINGS.—The Panel shall meet at the call of a major-  
2 ity of its members.

3 (B) FIRST MEETING.—The Panel shall convene not later than  
4 60 days after the date of the enactment of the Health Care Qual-  
5 ity and Choice Act of 1999.

6 (C) QUORUM.—A quorum shall consist of a majority of the  
7 members of the Panel.

8 (D) HEARINGS.—For the purpose of carrying out its duties,  
9 the Panel may hold such hearings and undertake such other activi-  
10 ties as the Panel determines to be necessary to carry out its du-  
11 ties.

12 (5) ADMINISTRATION.—

13 (A) COMPENSATION.—Except as provided in subparagraph  
14 (B), members of the Panel shall receive no additional pay, allow-  
15 ances, or benefits by reason of their service on the Panel.

16 (B) TRAVEL EXPENSES AND PER DIEM.—Each member of  
17 the Panel who is not an officer or employee of the Federal Govern-  
18 ment shall receive travel expenses and per diem in lieu of subsist-  
19 ence in accordance with sections 5702 and 5703 of title 5, United  
20 States Code.

21 (C) CONTRACT AUTHORITY.—The Panel may contract with  
22 and compensate government and private agencies or persons for  
23 items and services, without regard to section 3709 of the Revised  
24 Statutes (41 U.S.C. 5).

25 (D) USE OF MAILS.—The Panel may use the United States  
26 mails in the same manner and under the same conditions as Fed-  
27 eral agencies and shall, for purposes of the frank, be considered  
28 a commission of Congress as described in section 3215 of title 39,  
29 United States Code.

30 (E) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request  
31 of the Panel, the Secretary of Health and Human Services shall  
32 provide to the Panel on a reimbursable basis such administrative  
33 support services as the Panel may request.

34 (6) SUBMISSION OF FORM.—Not later than 2 years after the first  
35 meeting, the Panel shall submit a form to the Secretary of Health and  
36 Human Services for use by third-party health care payers.

37 (7) TERMINATION.—The Panel shall terminate on the day after  
38 submitting its the form under paragraph (6).

39 (b) REQUIREMENT FOR USE OF FORM BY THIRD-PARTY CARE PAY-  
40 ERS.—A third-party health care payer shall be required to use the form de-



- 1     vised under subsection (a) for plan years beginning on or after 5 years fol-
- 2     lowing the date of the enactment of this Act.